IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

	§	
	§	RELATOR BROOK JACKSON'S
UNITED STATES OF AMERICA	§	ORIGINAL COMPLAINT FOR
ex rel. Brook Jackson,	§	VIOLATIONS OF THE FEDERAL
	§	FALSE CLAIMS ACT
Plaintiff,	§	
	§	**FILED UNDER SEAL**
v.	§	PURSUANT TO 31 U.S.C. § 3730(b)(2)
	§	
	§	CASE NO. ________________
VENTAVIA RESEARCH GROUP, LLC;	§	
PFIZER INC.; ICON PLC,	§	DO NOT PUT ON PACER
	§	
Defendants.	§	DO NOT PLACE IN PRESS BOX
	§	
	§	JURY TRIAL DEMANDED
	§	

RELATOR BROOK JACKSON'S ORIGINAL COMPLAINT

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1. Plaintiff/Relator Brook Jackson ("Jackson" or "Relator") brings this action pursuant to the False Claims Act, 31 U.S.C. §§ 3729–3732, and seeks to recover all damages, penalties, and other remedies established by the False Claims Act on behalf of the United States of America and on her own behalf. Relator would respectfully show the following:

I. INTRODUCTION TO CASE

2. Developing a safe and effective vaccine against the novel Coronavirus ("COVID-19") was a matter of urgency. But that urgency does not excuse cutting corners in clinical trials, wasting taxpayer dollars, violating federal regulations, and possibly endangering Americans' health. Defendants Pfizer Inc., Icon PLC, and Ventavia Research Group, LLC (collectively, "Defendants") conducted a clinical trial to test one of the COVID-19 vaccine candidates. In the race to secure billions in federal funding and become the first to market, Defendants deliberately withheld crucial information from the United States that calls the safety and efficacy of their vaccine into question. Namely, Defendants concealed violations of both their clinical trial protocol and federal regulations, including falsification of clinical trial documents. Due to Defendants' scheme, millions of Americans have received a misbranded vaccination which is potentially not as effective as represented. The vaccine's U.S. Food and Drug Administration ("FDA") authorization resulted from a deeply flawed clinical trial that violated FDA regulations. Defendants have profited from the COVID-19 pandemic at the expense of the United States and its citizens by abusing the scientific process.

3. BioNTech SE ("BioNTech") and Defendant Pfizer Inc. ("Pfizer") co-developed a messenger RNA vaccine against COVID-19. After a reportedly successful Phase 1 clinical trial, Pfizer entered into a contract with the United States Department of Defense ("DoD"), under which DoD would purchase 100 million doses of the vaccine for $1.95 billion following FDA approval

or Emergency Use Authorization ("EUA"). Pfizer and BioNTech became co-sponsors of Phase 2 and 3 clinical trials for their vaccine, aiming for FDA approval or EUA status.

4. Pfizer delegated management of the clinical trial to subcontractor Defendant Icon PLC ("Icon"), an Irish clinical research organization. Icon was tasked with oversight of over 160 test sites worldwide, ensuring trial protocol compliance, and ensuring reporting of required information. This includes oversight of Serious Adverse Event ("SAE") reporting, which is required by the trial protocol and federal regulations. Pfizer remained responsible for managing and quality checking all data for the entire clinical trial, per the trial's protocol.

5. Defendant Ventavia Research Group, LLC ("Ventavia") was contracted by Pfizer to provide three Phase 3 test sites for the vaccine trial in Houston, Fort Worth, and Keller, Texas. Ventavia ultimately enrolled about 1,500 clinical trial patients. Ventavia employed Relator Jackson as a Regional Director. She was tasked with overseeing site management, patient enrollment, quality assurance completion, event reporting, corrective action plan creation, communication with management, and staff training completion at the Keller and Fort Worth sites.

6. Pfizer, aiming for the title of "first successful COVID-19 vaccine," pushed Ventavia to enroll as many patients as possible in the vaccine trial as quickly as possible. Ventavia was compensated by Pfizer mainly on a per-patient basis—up to a weekly limit—and rushed to enroll as many clinical trial participants as possible per week. Ventavia's race to maximize payment and over-booking of patients resulted in sloppy and fraudulent documentation practices, poor clinical trial protocol compliance, and little oversight. Pfizer and Icon turned a blind eye to Ventavia's misconduct, despite numerous warning signs.

7. Ventavia's trial protocol and regulatory violations were so widespread, in fact, that Relator observed them on a near-daily basis during her brief employment period. For example, Relator observed:

- fabrication and falsification of blood draw information, vital signs, signatures and other essential clinical trial data;
- enrollment and injection of ineligible clinical trial participants, including Ventavia employees' family members;
- failure to timely remove ineligible patients' data from the trial;
- failure to maintain temperature control for the vaccine at issue;
- failure to monitor patients after injection as required by the trial protocol;
- principal investigator oversight failures;
- use of unqualified and untrained personnel as vaccinators and laboratory personnel;
- failure to maintain the "blind" as required, which is essential to the credibility and validity of the observer-blinded clinical trial;
- ethical violations, such as failure to secure informed consent and giving patients unapproved compensation;
- improper injection of the vaccine (*i.e.*, by over-diluting vaccine concentrate or using the wrong needle size);
- failure to ensure that trial site staff were properly trained as required by good clinical practices;
- safety and confidentiality issues, including HIPAA violations; and
- other violations of the clinical trial protocol, FDA regulations, and Federal Acquisition Regulations and their DoD supplements.

8. Ventavia failed to report the majority of its clinical trial protocol and regulatory violations to Pfizer or the external Institutional Review Board. Issues were improperly documented or hidden away in "notes to the file," and not corrected.

9. Icon and Pfizer communicated with each trial site to monitor compliance, but failed to follow up on missing information, ignored "red flags" of trial protocol violations and false data, and failed to exclude ineligible participants from the trial data. In Pfizer's rush to be the "first," it failed to address violations that compromised its entire clinical trial, including those raised by Relator. This resulted in Pfizer withholding material information from the United States, and submitting false data and records in its clinical trial results.

10. Relator reported many of the violations she observed to Ventavia management, who allowed the majority of violations to continue unabated. Defendant Ventavia harassed Relator and terminated her in retaliation for her reports of and efforts to stop fraud against the United States DoD. Relator also reported her concerns to Pfizer after termination, yet Pfizer elected to press on, expanding its trial to include even more participants.

11. Although Relator's experience with test sites is limited to Texas, Pfizer and Icon's oversight failures and fraudulent misconduct vis-a-vis Ventavia bring the entire Pfizer-BioNTech clinical trial into question. It is likely that similar fraud occurred at clinical trial sites managed by other subcontractors of Pfizer.

12. The FDA issued EUA for the Pfizer-BioNTech vaccine on December 11, 2020. The EUA is based in part on Defendants' falsified clinical trial results and concealment of key information. As a result, DoD has now purchased misbranded vaccines from Defendant Pfizer, relying on Defendants' fraudulent misrepresentations that the vaccine trial was properly conducted. Had DoD known of Defendants' clinical trial protocol violations, fraudulent conduct, and regulatory violations, it would not have purchased the vaccines.

13. Defendants' fraudulent scheme caused DoD to pay billions that it would not have paid had it known that the safety and efficacy of the vaccine at issue was not properly proven. At worst, the vaccine could be far less effective than represented, and DoD has purchased something that will not protect the public from COVID-19 as effectively as claimed. At best, the vaccine is effective, but Defendants have profited from the COVID-19 pandemic by lying to the United States, violating federal regulations, and failing to uphold the integrity of the scientific process.

II. JURISDICTION AND VENUE

14. Jurisdiction and venue are proper in the Eastern District of Texas pursuant to 31 U.S.C. § 3732(a) because Relator's claims seek remedies on behalf of the United States for multiple violations of 31 U.S.C. §§ 3729–3732 in Texas by Defendants that damaged the United States government.

15. Defendants Pfizer, Inc. and Ventavia do business in Texas and are registered with the Texas Secretary of State.

16. Defendant Icon PLC conducts continuous and systematic business in Texas. It maintains corporate offices in San Antonio and Sugar Land, Texas, and employs hundreds of Texans statewide, including in this District. Icon PLC also oversees and manages clinical trial sites in Texas and in this District.

17. Defendants are therefore subject to general and specific personal jurisdiction pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1367.

III. GOVERNMENT PLAINTIFF

18. The Government Plaintiff in this lawsuit is the United States of America.

IV. INTRODUCTION TO RELATOR BROOK JACKSON

A. Relator's Background

19. Relator Brook Jackson ("Relator" or "Jackson") has worked in the clinical trials field for over eighteen years. She is a Clinical Research Auditor and Certified Clinical Research Professional. Before working for Defendant Ventavia Research Group, LLC ("Ventavia"), Jackson served as the Director of Operations for a multi-state clinical trial company. Second only to the CEO, she oversaw legal and regulatory compliance, adherence to good clinical practices, submission of required documentation, and business development across the company.

20. Because Relator's prior position required a great deal of travel, she decided to leave that company and begin working for Ventavia. Relator began her employment with Ventavia on September 8, 2020 as a Regional Director.

21. As Regional Director, Relator oversaw site managers, patient recruitment success, training completion, quality assurance completion, enforcement of communication paths, and growth plans at her assigned test sites. Relator's job duties also included daily and weekly communication with the site operations managers of her assigned test sites and Ventavia's leadership team. Relator was responsible for the duties above at two of Ventavia's three test sites for the clinical trial at issue, located in Fort Worth and Keller, Texas.

22. Relator's direct supervisor during her employment with Ventavia was Director of Operations Marnie Fisher ("Fisher"). Her other superiors were Ventavia's Executive Directors Olivia Ray ("Ray") and Kristie Raney ("Raney") and the Chief Operating Officer, Mercedes Livingston ("Livingston").

23. Beginning on September 8, 2020, Relator reported on a near-daily basis to Fisher and Livingston that patient safety and the integrity of the Pfizer-BioNTech vaccine trial was at risk, via telephone, conversation, and e-mail. Relator discussed virtually all of the clinical trial protocol and FDA regulatory violations she witnessed with Livingston, Ray, Raney, and Fisher, including, but not limited to: (1) enrollment and injection of ineligible trial participants; (2) falsification of data, poor recordkeeping, and the deficiency of Ventavia's documentation "quality control"; (3) deficiencies in and failure to obtain informed consent from trial participants; (4) adverse event capture and reporting; (5) failure to preserve blinding; (6) vaccine dilution errors; (7) failure to list all staff on delegation logs; (8) principal investigator oversight; (9) reporting temperature excursions; (10) patient safety issues, such as not keeping epinephrine dose

information in patient charts; (11) failure to secure and record staff training required by clinical research standards; (12) use of unqualified staff as vaccinators; (13) use of biohazard bags for needle disposal; and (14) failure to properly monitor patients post-injection.

24. In general, every time that Relator raised concerns about safety or Ventavia's clinical trial protocol compliance with Fisher, she was told to e-mail Fisher about the issue or make a list of affected patients. Many of the identified issues were systemic, and Relator did not always have access to information required to make the lists Fisher requested. Relator did as Fisher requested to the extent that she was able, but the identified problems were never addressed.

25. Relator also reported some clinical trial protocol violations to the Fort Worth Principal Investigator, Dr. Mark Koch. In particular, Relator discussed Ventavia's practice of "quality checking" patient source documents long after the fact and issues of missing documentation. Dr. Koch acknowledged that Ventavia needed to "clean up" the problems before starting any new clinical trials.

26. Ventavia was required to scan or enter all data from clinical trial participants' source documents into the "Complion" Clinical Trial Management System database, so that it could be passed on to Icon and Pfizer. Ventavia "quality checked" all source documents before scanning or uploading them. In Ventavia's scramble to enroll as many participants as possible, quality checking and uploading fell behind schedule. Relator observed that the "back log" of documents to be quality checked often lacked key information, such as patient or doctor signatures and blood draw times. Relator also observed that Ventavia's quality checking process was performed by unqualified personnel not listed on delegation logs, and often involved falsification of missing data. Relator reported her concerns to Ventavia management, who was more concerned with "catching up" on quality checking than actually solving the problem.

27. On September 16, 2020, Relator examined some of the biohazard disposal bags at Ventavia's Fort Worth site. Relator discovered that used needles had been disposed of in the bags. Biohazard bags are not puncture-proof, so this presented a serious risk to employees' safety. That same night, Relator photographed ongoing HIPAA violations. Relator also documented that product cartons and patient randomization numbers from the BioNTech-Pfizer vaccine trial had been left in public view in a preparation area, potentially unblinding all Ventavia staff at the site and some patients as well. Relator shared her photographs from September 16 with Livingston and Fisher via text message or e-mail.

28. On September 17, 2020, in her daily phone call with Ray, Raney, Fisher, Livingston, and Houston Regional Director Lovica "Kandy" Downs ("Downs"), Relator brought up virtually all of the protocol and regulatory violations she had witnessed to date, as well as Ventavia's HIPAA violations. Relator explained that the FDA would likely issue warning letters against Ventavia if it visited or audited the trial sites. She recommended that Ventavia immediately stop enrollment in the Pfizer-BioNTech clinical trial.

29. Ventavia shortly thereafter decided to pause enrollment in order to catch up on "quality checking" source documents. Ventavia was not up-front with Pfizer and Icon about the reasons for the enrollment pause (sloppy documentation that violated the clinical trial protocol). Ventavia elected to schedule patients for several weeks later rather than truly and completely pause enrollment. *See* Ex. 1, Text Messages with Ray and Others, at 6, 9–10. Raney directed employees not to cancel any patients already "on their way" to test sites because "that might piss them off and they can call the news, etc[.]" Ex. 1, at 11.

30. During the enrollment pause, Ventavia's "quality checking" not only failed to correct documentation violations but also involved falsification of missing or inconsistent data.

Relator even personally observed employees falsifying source document data (*i.e.*, by changing blood pressure readings). In short, Ventavia's "quality checking" failed to prevent or stop fraud on the United States DoD.

31. On September 23, 2020, Relator e-mailed Ray, Fisher, Raney, Downs, Livingston, and Director of Quality Control William Jones ("Jones") to report ongoing serious issues with Ventavia's "quality checking." *See* Ex. 2, E-mail Chain with Ray and Others (Sept. 23, 2020). Relator noted, for example, that multiple patients had not received their second dose of the vaccine in the required window of nineteen to twenty-three days, and that Ventavia had not truthfully recorded the delay. *Id.* Due to the seriousness of these violations, Relator stated, "I might be in a little bit of shock." Ex. 2, at 1.

32. On the evening of September 24, 2020, Relator met with Fisher and Jones. *See* Ex. 3, Transcript of September 24, 2020 Meeting Recording. The meeting was arranged to discuss Relator's photographic documentation of safety issues, HIPAA violations, and unblinding from September 16. The meeting quickly escalated into harassment. Fisher questioned repeatedly why Relator took the photographs and falsely accused Relator of removing patient source documents from another Ventavia location. Jones stated that Ventavia had not "even finished quantifying the number of errors" because "it's something new every day." Ex. 3, at 12. He acknowledged that the problems were "not just in one site" either, and stated "we're gonna get some kind of letter of information at least, when the FDA gets here. Know it." *Id.*

33. Relator specifically referenced FDA regulatory violations in her September 24 conversation with Fisher and Jones. She told Fisher and Jones that if they did not see what she saw when quality checking patients' source documents, then they needed to "get on Google" and search for FDA warning letters. Ex. 3, at 14. Relator also reported to Fisher and Jones that Raney

and Ray had acknowledged that Ventavia did not have the staff or patient room capacity to handle the number of clinical trial participants being seen every day.

34. On the following morning, Relator called the FDA's hotline to report the clinical trial protocol violations and patient safety concerns she witnessed. Relator was terminated from her position at Ventavia that same day—September 25, 2020—under the pretext that she was "not a good fit." Relator had never been formally disciplined or reported for any failure regarding her job performance.

35. After Relator was terminated, she called Ventavia's contact at Pfizer and gave a general overview of her concerns about unblinding, principal investigator oversight, and patient safety in the Pfizer-BioNTech vaccine trial. She also informed Pfizer that she had contacted the FDA.

36. Almost immediately after Relator was terminated (the next business day), Ventavia lifted the enrollment "pause" and resumed the push to enroll as many clinical trial participants per week as possible. Given the amount of quality checking left to be performed when Relator was terminated, Relator estimates that Ventavia had neither completed quality checking nor remedied its ongoing violations by the time it resumed enrollment.

37. Ventavia retaliated against Relator in response to her reports of, and efforts to stop, fraud against the United States DoD resulting from the Pfizer-BioNTech COVID-19 vaccine trial.

B. Original Source and Disclosures

38. There are no bars to recovery under 31 U.S.C. § 3730(e), and, or in the alternative, Relator is an original source as defined therein. Relator has direct and independent knowledge of the information on which she bases her allegations. To the extent that any allegations or transactions herein have been publicly disclosed, Relator has independent knowledge that

materially adds to any publicly disclosed allegations or transactions and has provided this information to the United States and DoD prior to filing a complaint by serving a voluntary pre-filing disclosure statement.

39. Relator will submit an original disclosure statement, as well as substantially all material evidence and information, to the Attorney General of the United States, Department of Justice, and United States Attorney for the Eastern District of Texas contemporaneously with the service of this Original Complaint.

V. DEFENDANTS

A. Pfizer Inc.

40. Pfizer Inc. ("Pfizer") is a Delaware corporation headquartered at 235 East 42nd Street, New York, New York 10017-5703. It maintains an office in this District at 1301 Solana Boulevard, Westlake, Texas 76262. Pfizer, together with BioNTech, developed the vaccine at issue and co-sponsors the clinical trial at issue.

41. Pfizer is publicly-traded on the New York Stock Exchange under the ticker symbol "PFE."

42. The United States Department of Defense has contracted with Pfizer to purchase 200 million doses of the vaccine at issue after FDA approval, for a total cost of $3.9 billion.

43. Pfizer is currently subject to a Corporate Integrity Agreement with the Office of the Inspector General of the U.S. Department of Health and Human Services, dated May 23, 2018.[1]

44. Pfizer may be served through its registered agent, CT Corporation System, at 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

[1] *Available at* https://oig.hhs.gov/fraud/cia/agreements/Pfizer_Inc_05232018.pdf

B. Icon PLC

45. Icon PLC ("Icon") is an Irish company headquartered in Dublin. Icon conducts extensive business in the United States and Texas, including at its offices in Sugar Land and San Antonio, Texas. Icon has hundreds of employees in Texas, including in this District, and oversees and manages clinical trials statewide.

46. Icon is publicly-traded on the NASDAQ stock exchange under the ticker symbol "ICLR."

47. Defendant Pfizer subcontracted Icon to manage the clinical trial at issue. Icon oversaw more than 160 test sites worldwide, and was tasked with ensuring clinical trial protocol compliance and required information reporting.

48. Icon may be served at South County Business Park, Leopardstown, Dublin 18, Ireland.

C. Ventavia Research Group, LLC

49. Ventavia Research Group, LLC ("Ventavia") is a Texas limited liability company headquartered at 1307 Eighth Avenue, Suite 202, Fort Worth, Texas 76104. Ventavia operates ten test sites in Texas, some of which are located in this District. Three of Ventavia's test sites—in Keller, Fort Worth, and Houston—participated in the vaccine trial at issue.

50. Ventavia secured its contract to operate three test sites for the Pfizer-BioNTech vaccine trial through its contracting agent Platinum Research Network, LLC, and was paid directly by Defendant Pfizer for that work. Pfizer compensated Ventavia mainly on a per-patient basis, with additional amounts paid per Serious Adverse Event reported and for activities like training.

51. Ventavia recorded all key participant and clinical trial information in "source documents" made available to Pfizer and Icon after entry or upload.

52. Ventavia may be served through its registered agent, Registered Agents Solutions Inc., at 1701 Directors Boulevard, Suite 300, Austin, Texas 78744.

VI. RESPONDEAT SUPERIOR AND VICARIOUS LIABILITY

53. Any and all acts alleged herein to have been committed by Defendants were committed by officers, directors, employees, representatives, or agents, who at all times acted on behalf of Defendants and within the course and scope of their employment, or by corporate predecessors to whom successive liability applies.

VII. STATUTORY AND FACTUAL BACKGROUND

A. COVID-19 Vaccine Development

54. On May 15, 2020, the White House announced Operation Warp Speed ("OWS"), a partnership between the United States Department of Health and Human Services ("HHS") and the United States Department of Defense ("DoD").

55. OWS aimed to begin delivery of 300 million doses of FDA-authorized COVID-19 vaccines by January of 2021. HHS, Fact Sheet: Explaining Operation Warp Speed (Nov. 30, 2020).[2] OWS coordinates with and expands existing HHS programs, including the National Institutes of Health's Accelerating COVID-19 Therapeutic Interventions and Vaccines ("ACTIV") partnership. *Id.*

56. OWS's main initiative has been contracting with pharmaceutical companies to fund clinical trials of or purchase promising COVID-19 vaccine candidates. Purchases only occur after those vaccine candidates secure approval or Emergency Use Authorization from the United States Food and Drug Administration ("FDA"). The vaccine at issue is part of one such contract, explained further *infra*.

[2] https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html.

B. FDA Clinical Trial Regulations

57. The FDA promulgates regulations applicable to all clinical trials of new drugs like the vaccine at issue. *See* 21 C.F.R. §§ 312.1 *et seq.* These regulations apply with equal force to COVID-19 vaccine trials, despite their accelerated nature and the pandemic emergency. *See* 42 U.S.C. § 247d-6d(c)(5)(C)(i).

58. Clinical trial sponsors like Pfizer must submit an Investigational New Drug Application ("IND") before commencing the trial. *See* 21 C.F.R. § 312.23(a). An example IND (Form FDA-1571) is attached hereto as Exhibit 4. In the IND, the sponsor commits to conduct the trial "in accordance with all [] applicable regulatory requirements." 21 C.F.R. § 312.23(a)(v); Ex. 4, Form FDA-1571, at 2. The IND form warns clinical trial sponsors that making a "willfully false statement is a criminal offense." Ex. 4, at 2.

59. Clinical trial sponsors must utilize an Institutional Review Board ("IRB") for initial and continuing review and approval of the clinical trial. *See* 21 C.F.R. § 312.23(a)(iv). The sponsor must report "all changes in the research activity" to the IRB, along with "all unanticipated problems involving risk to human subjects or others." 21 C.F.R. § 312.66. The sponsor must assure that it "will not make **any changes to research without IRB approval**, except where necessary to eliminate apparent immediate hazards to human subjects." *Id.* (emphasis added).

60. The sponsor must promptly investigate "all safety information it receives" and follow up on any adverse reactions. 21 C.F.R. § 312.32(d)(1). The sponsor must also review all safety and effectiveness information reported by contract investigators (*i.e.*, clinical trial sites). The sponsor must notify the FDA of potential serious risks and adverse reactions. *See* 21 C.F.R. § 312.32(c).

61. If a study sponsor utilizes contract investigators for its clinical trial (like how Pfizer contracted with Icon and Ventavia here), it must ensure that the investigator is qualified, provide the investigator with the information needed to properly conduct a clinical trial, ensure proper monitoring of the trial, ensure that the trial complies with the IND and clinical trial protocol, and ensure "that FDA and all participating investigators are promptly informed of significant new adverse effects or risks" with respect to the drug under investigation. 21 C.F.R. § 312.50.

62. The sponsor must obtain a signed Form FDA-1572 from each contract investigator. 21 C.F.R. § 312.53(c). In Form FDA-1572, each investigator certifies, in relevant part, that it:

> (a) Will conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, the rights, or welfare of subjects;
> (b) Will comply with all requirements regarding the obligations of clinical investigators and all other pertinent requirements in [21 C.F.R. part 312];
> (c) Will personally conduct or supervise the described investigation(s);
> (d) Will inform any potential subjects that the drugs are being used for investigational purposes and will ensure that the requirements relating to obtaining informed consent (21 CFR part 50) and institutional review board review and approval (21 CFR part 56) are met;
> (e) Will report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with § 312.64; . . . [and]
> (g) Will ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

21 C.F.R. § 312.53(c)(vi); *see also* Ex. 5, Form FDA-1572. Each contract investigator also commits in Form FDA-1572 to promptly report to the IRB "all changes in the research activity and all unanticipated problems involving risks to human subjects or others[.]" 21 C.F.R. § 312.53(c)(vii). The contract investigators further commit to not making any research changes without IRB approval "except where necessary to eliminate apparent immediate hazards to the human subjects." *Id.* The Form warns contract investigators that a "willfully false statement is a criminal offense." Ex. 5, at 2.

63. The sponsor must monitor its contract investigators' progress and compliance with the clinical trial protocol, IND, and all applicable regulations. *See* 21 C.F.R. §§ 312.50, 312.56. "A sponsor who discovers that an investigator is not complying" with those requirements "shall promptly either secure compliance or discontinue shipments of the investigational new drug to the investigator and end the investigator's participation in the [clinical trial]." 21 C.F.R. § 312.56(b). Contract investigators are bound by the same regulations as the sponsor, to the same degree, with regard to any obligation the sponsor delegates to them. *See* 21 C.F.R. § 312.52.

64. Thus, in the clinical trial at issue, all Defendants are bound by FDA regulations and "subject to the same regulatory action . . . for failure to comply[.]" 21 C.F.R. § 312.52(b). Failure to comply with FDA regulations or submission of false information to the trial sponsor or FDA can disqualify a company from conducting future clinical trials. *See* 21 C.F.R. § 312.70(b).

65. Contract investigators are obligated to "furnish all reports to the sponsor." 21 C.F.R. § 312.64(a). The sponsor "is responsible for collecting and evaluating the results obtained." *Id.*

66. Contract investigators must maintain adequate records of drug dispensation, "including dates, quantity, and use by subjects." 21 C.F.R. § 312.62(a). They must also keep "adequate and accurate case histories" for all study participants which "record all observations and other data pertinent to the investigation[.]" 21 C.F.R. § 312.62(b).

67. Informed consent must be obtained and documented for every participant in the clinical trial. *See* 21 C.F.R. §§ 50.27(a), 312.60, 312.62(b). The investigator must document "that informed consent was obtained **prior to** participation in the study." 21 C.F.R. § 312.62(b) (emphasis added).

68. The clinical trial drug (here, the vaccine at issue) shall only be given to subjects under an investigator or sub-investigator's personal supervision. *See* 21 C.F.R. § 312.61. It shall not be given to any person not authorized to receive it. *Id.*

69. Contract investigators must immediately report any Serious Adverse Event ("SAE") to the sponsor, "whether or not considered drug related, . . . and must include an assessment of whether there is a reasonable possibility that the drug caused the event." 21 C.F.R. § 312.64(b). Nonserious adverse events must also be reported to the sponsor. *Id.*

70. SAEs have the potential to pause clinical trials if sufficiently serious. *See* 21 C.F.R. § 312.44. In fact, two of Pfizer's competitors in the COVID-19 vaccine race—Astra Zeneca and Johnson & Johnson—had to pause their own clinical trials when participants developed unexplained illnesses.

C. The BioNTech-Pfizer COVID-19 Vaccine

1. Background and Development of BNT162b2

71. BNT162b2, the vaccine at issue, is a biologic vaccine co-developed by BioNTech and Defendant Pfizer which is based on a platform of nucleoside-modified messenger RNA ("mRNA").

72. Most conventional vaccines are based on weakened strains of the virus at issue. Those vaccines essentially "teach" the body how to fight the weakened virus, resulting in production of antigens to combat future infection.

73. BNT162b2, in contrast, is based on mRNA—molecules of genetic material—from the novel Coronavirus. The vaccine causes the body's cells to produce viral proteins, and the body then produces an immune response. In this way, the body is "taught" how to fight the virus's proteins, rather than a weakened version of the virus itself. One purported advantage of mRNA

vaccines is that there is no risk of infection because they do not contain the actual virus—just parts of its genetic material.

74. One drawback of mRNA vaccines like BNT162b2—and one reason that they are not widespread—is that they must be stored at more controlled temperatures than conventional vaccines. BNT162b2 specifically must be stored in medical-grade freezers at –112°F to –76°F. It may also be shipped and stored short-term in a specialized cooler with dry ice (solid carbon dioxide) for up to ten days unopened.

75. Because BNT162b2 is stored at such low temperatures, it must be thawed before use. The placebo used in the BNT162b2 clinical trial does not require such thaw time. In order to preserve patient blinding in the BNT162b2 clinical trial, waiting times for both the vaccine and placebo are standardized at thirty minutes or more, and the syringe is covered by an opaque label during injection. *See* Ex. 6, BNT162b2 Product Manual, at 34, 48–49.

2. Clinical Trial Overview

76. Clinical trials of new drugs are divided into three phases under FDA regulations. *See* 21 C.F.R. § 312.21. Phase 1 trials typically evaluate the "metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, . . . gain early evidence on effectiveness." 21 C.F.R. § 312.21(a)(1).

> Phase 2 includes the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects.

21 C.F.R. § 312.21(b). Next, Phase 3 trials are "performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the

drug and to provide an adequate basis for physician labeling." 21 C.F.R. § 312.21(c). Phase 3 trials "usually include from several hundred to several thousand subjects." *Id.*

77. Phase 1 of the trial at issue concluded in the summer of 2020. It involved 195 United States participants aged eighteen to fifty-five. Several different doses were tested, and the most successful, called "BNT162b2," was advanced to Phase 2 and 3 testing. *See* Edward E. Walsh et al., *Safety & Immunogenicity of 2 RNA-Based COVID-19 Vaccine Candidates*, New England Journal of Medicine (Oct. 14, 2020).[3]

78. In Phase 2 and 3 of the trial, the vaccine at issue was administered as an intramuscular injection. The clinical trial protocol requires that it be administered in two doses separated by nineteen to twenty-three days. Ex. 7, Clinical Trial Protocol, at 88; Ex. 6, BNT162b2 Product Manual, at 45.

79. Pfizer expanded the trial to HIV-positive individuals, those with Hepatitis B and C, and sixteen- and seventeen-year-olds in September of 2020, adding 14,000 new participants worldwide. Pfizer again expanded the trial to young teenagers (aged twelve to fifteen) on October 12, 2020, adding approximately 4,400 more participants.

80. A total of 43,998 participants were enrolled in Phase 3 of the trial at issue, per Pfizer's reporting on clinicaltrials.gov.[4] Approximately 1,500 of those were enrolled at Defendant Ventavia's facilities. Defendant Ventavia recruited study participants via advertising, contacting local business and organizations, and features in local news media. Patients were paid for participation in the study.

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[3] https://www.nejm.org/doi/10.1056/NEJMoa2027906?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.
[4] https://clinicaltrials.gov/ct2/show/study/NCT04368728.

81. Pfizer and BioNTech announced the completion of Phase 3 on November 18, 2020. Ex. 8, Pfizer Press Release, at 2. Pfizer applied for EUA for BNT162b2 on November 20, 2020. The FDA granted EUA on December 11, 2020.[5]

3. Clinical Trial Protocol

82. Pfizer has publicized its clinical trial protocol on the Internet, and it is attached hereto as Exhibit 7. The protocol portions most relevant to this matter are summarized below.

a. Inclusion and Exclusion Criteria

83. The trial at issue is randomized, placebo-controlled, and observer-blinded. *See* Ex. 7, Clinical Trial Protocol, at 1. By the end of Phase 3, the trial included healthy individuals, aged twelve to eighty-five, at risk of acquiring COVID-19, who are capable of informed consent and willing and able to comply with scheduled visits, vaccination plan, laboratory tests, and study procedures. *See* Ex. 7, at 40–41. Individuals with certain pre-existing conditions or history are excluded, including pregnant and breastfeeding women and people with a history of severe vaccine reactions. *See* Ex. 7, at 41–43.

84. The study also excludes "[i]nvestigator site staff or Pfizer/BioNTech employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members." Ex. 7, at 43.

85. Participants who have already begun the study must be withdrawn if they deviate from the protocol, lose their eligibility, or take certain medications. *See* Ex. 7, at 50–53. Participants who become pregnant after receiving the first dose of the vaccine, for example, must withdraw from the study. *See* Ex. 7, at 65.

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[5] Press Release, FDA, FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine (Dec. 11, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.

86. All participants' eligibility screening evaluations must be reviewed "to confirm that potential participants meet all eligibility criteria." Ex. 7, at 55. Ventavia was required to "maintain a screening log to record details of all participants screened and to confirm eligibility or record reasons for screening failure, as applicable." *Id.*

87. Each participant's full date of birth must be collected in order to facilitate evaluation of immune response and safety by age. Ex. 7, at 54.

b. Blinding

88. The study is observer-blinded. Ex. 7, at 1. The physical appearance of the vaccine and placebo differ, so blinding the person administering the vaccine is not possible. *See* Ex. 7, at 36. The patient receiving the vaccine, study coordinator, and other site staff are blinded. *See* Ex. 7, at 36, 48–49.

89. At the test site level, the only people who should be unblinded are those administering the injection. *See* Ex. 7, at 36, 48–49. Nobody involved in "evaluation of any study participants" should be unblinded. Ex. 7, at 49.

c. Temperature Control

90. The investigator must confirm that all vaccine doses received have been transported and stored under "appropriate temperature conditions[,]" and that "any discrepancies are reported and resolved before use of the study intervention." Ex. 7, at 47.

91. The vaccines must be stored in "a secure, environmentally controlled, and monitored" area in accordance with the product manual, as described further *infra*. *Id.* Daily maximum and minimum temperatures must be recorded for all storage locations and those records must be made available upon request. *See id.*

92. Any deviations from recommended temperature, called "temperature excursions," must be reported to Pfizer upon discovery, "along with any actions taken." Ex. 7, at 47. The vaccines subject to the excursion must be quarantined from others and not used unless Pfizer subsequently provides permission. *See id.*

d. Informed Consent

93. As with all clinical drug trials, the participant must provide informed consent. The protocol for the trial at issue requires obtaining signed and dated informed consent documentation prior to performing *any* study-specific procedures, including administration of the vaccine. *See* Ex. 7, at 54, 117.

e. Administration

94. Before administration of the vaccine, study participants receive a clinical assessment "to establish a baseline." Ex. 7, at 58. The participant's medical history and observations from any physical examination must be documented and submitted to Pfizer. *See id.*

95. Women of childbearing potential must undergo a pregnancy test before receiving the vaccine or placebo. *See* Ex. 7, at 23, 65,

96. Only participants enrolled in the study may receive the vaccine, and only authorized site staff may administer it. Ex. 7, at 47.

97. Study participants must receive the vaccine "under medical supervision." Ex. 7, at 50. The date and time of injection must be recorded. *Id.*

98. Participants must receive their second injection nineteen to twenty-three days after the first. *See* Ex. 7, at 23, 88.

f. Safety and Monitoring

99. All adverse events in the first thirty minutes after injection must be documented in an Adverse Event Case Report Form. *See* Ex. 7, at 58, 86, 89.

100. Participants use an electronic diary ("e-diary") application to record any adverse events and use of any antipyretic (fever-reducing) medication. *See* Ex. 7, at 58–59. E-diary data is periodically transmitted directly to Pfizer and Icon. *See* Ex. 7, at 59.

101. After participants report any ongoing local reactions, systemic events, or use of antipyretic medication, the investigator must obtain and document end dates for those events. *See* Ex. 7, at 59–60.

102. Serious adverse events ("SAEs") must be reported to Pfizer within twenty-four hours. Ex. 7, at 66. Under no circumstances should they be reported later. *Id.* Any update to SAE information must be reported to Pfizer within twenty-four hours of it becoming available. *Id.* Any non-serious adverse events must be reported and documented on Case Report Forms submitted to Pfizer. *See id.* Site investigators are responsible for pursuing and obtaining "adequate information both to determine the outcome and to assess whether the event" is serious "or caused the participant to discontinue the study intervention." Ex. 7, at 65.

103. Follow-up on adverse events must continue until the event resolves or stabilizes at a level acceptable to the investigator and concurred with by Pfizer. *Id.* Follow-up information must include enough detail to allow for complete medical assessment and independent determination of possible causality. Ex. 7, at 67.

104. If any participant is confirmed to have been injected while pregnant or breastfeeding, Pfizer must be notified within twenty-four hours. *See* Ex. 7, at 67–68. The same

applies to pregnancy in partners of clinical trial participants. *Id.* The investigator must conduct follow-up on the pregnancy and its outcome and keep Pfizer updated. *See* Ex. 7, at 68–69.

g. Legal and Regulatory Compliance

105. The protocol emphasizes that investigators must notify Pfizer of SAEs "so that legal obligations and ethical responsibilities towards the safety of participants and the safety of [the vaccine] under clinical investigation are met." Ex. 7, at 67. The protocol notes that Pfizer "has a legal responsibility to notify" the government about the safety of the vaccine under investigation, and "will comply with country-specific regulatory requirements relating to safety reporting to the appropriate regulatory authority . . . and investigators." *Id.*

106. The protocol also states that the study will be conducted in accordance with all applicable laws and regulations, including privacy laws. Ex. 7, at 116.

107. Ventavia is responsible for oversight of the study at their sites and adherence to FDA regulations found in Title 21 of the Code of Federal Regulations. *See id.*

h. Adherence to Protocol

108. Adherence to the trial protocol "is essential and required for study conduct." Ex. 7, at 54. "Protocol waivers or exemptions are not allowed." *Id.* Thus, as noted previously, participants who deviate from the protocol must be excluded.

109. The protocol also requires that the clinical trial adhere to "ICH GCP"—Good Clinical Practices established by the International Council for Harmonization. *See* Ex. 7, at 116, 138–39.

110. Any failure to provide a test or procedure required by the protocol must be documented, alongside any corrective or preventive actions taken by the administrator, and Pfizer's safety team must be informed. *See* Ex. 7, at 55.

111. Site investigators must inform Pfizer immediately if they know of any new information which might influence the evaluation of the benefits and risks of the vaccine at issue. Ex. 7, at 116. They must also immediately inform Pfizer of any serious breaches of the study protocol or ICH GCP. *Id.*

112. Pfizer may close a study site early for any reason, including when the site investigator fails to comply with the study protocol. *See* Ex. 7, at 121.

i. Accuracy of Data

113. Site investigators must maintain accurate source documentation supporting all information entered into electronic Case Report Forms submitted to Pfizer. *See* Ex. 7, at 119–21. If source documents differ from any information in the Case Report Form, the discrepancy must be explained. Ex. 7, at 120.

114. Site investigators must verify that data entries are accurate and correct by signing the Case Report Forms transmitted to Pfizer. Ex. 7, at 119.

115. Pfizer or Icon is responsible for data management of the study, "including quality checking of the data." Ex. 7, at 120.

4. BNT162b2 Product Manual

116. The product manual for BNT162b2—attached hereto as Exhibit 6—provides specifics as to how the vaccine and placebo should be stored and administered. These specifics supersede storage conditions set out in the clinical trial protocol, and provide additional guidance for temperature excursions and use. *See* Ex. 7, Clinical Trial Protocol, at 47–48, 52, 80, 86, 88. Thus, noncompliance with the product manual is equivalent to noncompliance with BNT162b2's clinical trial protocol.

a. Additional Blinding Precautions

117. The patient, study coordinator, and other test site staff are blinded, as previously noted. The vaccinator is not. "Blinded personnel should not have access to the container IDs" for the vaccine. Ex. 6, Product Manual, at 23. "Only the site staff who will be dispensing, preparing, and administering the [vaccine] are unblinded and can have this access." *Id.*

118. Occluding labels are applied to the syringe barrel in order to mask its contents and preserve blinding. *See* Ex. 6, at 49–50. Patients are also instructed to look away during injection. *See* Ex. 6, at 50.

119. Each prepared BNT162b2 syringe expires six hours after preparation. Ex. 6, at 49. To preserve the blind, both the vaccine and placebo are given the same expiration date and time. *Id.*

120. Sites must have a process in place for maintaining the study blind, including ensuring that vials, dilution material, and dosing syringes "are shielded from the view of BLINDED study staff and the participant during dose preparation, dispensing, transportation, administration, and disposal." Ex. 6, at 49. The site should "ensure that the study blind was maintained and that the [BNT162b2] cartons, preparation records, syringes, and disposal of used supplies were carefully handled prior to and after administration." *Id.* The site must document for each participant whether the blind was maintained. *See* Ex. 6, at 50.

121. Pfizer must be notified of any potential unblinding, and further enrollment and injection must stop immediately:

> if the study drug is not stored, handled, or administered according to the protocol and/or relevant site documentation to adequately maintain the blind. The site must provide details of the incident or any protocol deviations and[] assist in resolving the issue and/or determining corrective actions to take.

> If the blind is broken or potentially broken, unblinded staff must contact [Pfizer] immediately. Do not administer or dispense the study drug to any participant and do not randomize a new participant until the Sponsor provides further instructions.

Ex. 6, at 43.

b. Temperature Excursions

122. BNT162b2 must be protected from light and stored at -112°F to -76°F in its original packaging prior to use in dose preparation. *See* Ex. 6, at 36, 40.

123. BNT162b2 is shipped in a specialized container with dry ice (solid carbon dioxide). Ex. 6, at 36. The shipping containers used in the clinical trial included a monitoring device that triggered an alarm if the acceptable temperature range for the product was exceeded. *See* Ex. 6, at 36, 38.

124. If any deviation in temperature for BNT162b2 shipments outside of the accepted range occurs, the product must be segregated and the excursion must be reported to Pfizer. *See id.*; Ex. 7, Clinical Trial Protocol, at 47. Pfizer then notifies the site if the product is acceptable for use despite the excursion. *See* Ex. 6, at 38.

125. The same process must be followed if there is any lapse in temperature monitoring or even when the site is not sure if there has been a temperature excursion. *See* Ex. 6, at 40.

c. Dose Preparation

126. BNT162b2 is shipped as a frozen concentrate, which is thawed for approximately 30 minutes and diluted with sodium chloride (saline) solution before injection. Ex. 6, at 47. "Only clinical site personnel who are appropriately trained on the procedures" in the product manual may prepare and administer BNT162b2. Ex. 6, at 46.

127. The doses must be allowed to reach room temperature before administration. Ex. 6, at 48. Preparation time is standardized at thirty minutes or more in order to avoid unblinding,

since the placebo has no thaw time. *See* Ex. 6, at 47–49, 53, 56, 60, 72, 76; Ex. 9, E-mail Chain with Downs and Others (Sept. 18, 2020), at 2.

d. Injection

128. Participants are injected using a 1" or 1.5" needle, depending on their body weight. Ex. 6, at 51. A 5/8" needle may also be used for participants weighing less than 130 pounds if the skin is stretched tightly. *Id.* The 1" needle size is appropriate for all participants except males over 260 pounds and females over 200 pounds, for whom a 1.5" needle is required. *See id.*

129. Only "an appropriately qualified and experienced member of the study staff" may prepare and administer the vaccine or placebo. Ex. 6, at 44, 72, 75, 78. The product manual specifies that this must be a "nurse, physician's assistant, nurse practitioner, pharmacy assistant/technician, or pharmacist[,] as allowed by local, state, and institutional guidance." *Id.*

130. The vaccine is injected into the deltoid muscle of the participant's non-dominant arm. Ex. 6, at 44.

131. Any error in dispensing the vaccine that may cause or lead to patient harm while in the site's control must be reported to Pfizer and Icon immediately. Ex. 6, at 62.

e. Monitoring

132. "Blinded site staff must observe" clinical trial participants after injection "for at least 30 minutes" to monitor "for any acute reactions." Ex. 6, at 44; *see also* Ex. 6, at 61. Reactions must be recorded in source documents, on an adverse event reporting form, and also as an SAE if necessary. Ex. 6, at 44.

D. Contract at Issue

1. Background

133. On July 21 2020, the United States DoD entered into the contract at issue with Defendant Pfizer, through Advanced Technology International ("ATI"). *See* Ex. 10, Pfizer-DoD Contract, at 1.

134. DoD likely used ATI as its intermediary in order to simplify the contracting process and avoid possible delay resulting from typical procurement processes. Despite the use of an intermediary, the United States has clearly stated that the contract is between itself and Pfizer. *See* Ex. 10, Pfizer-DoD Contract, at 1, 2; Press Release, HHS, U.S. Government Engages Pfizer to Produce Millions of Doses of COVID-19 Vaccine (July 22, 2020).[6]

135. Under the contract, DoD purchased 100 million doses of the vaccine at issue, with the option to purchase up to 500 million more doses later. *See* Ex. 10, at 11–12, 17. DoD contracted to pay Pfizer $1.95 billion for the vaccines ($19.50 per dose) after FDA approval or Emergency Use Authorization ("EUA"). *See* Ex. 10, at 1, 17.

136. The clinical trial at issue, which was privately-funded, aimed to secure FDA approval or EUA of the vaccine by the end of 2020, resulting in DoD's purchase of the vaccine and payment to Pfizer under the contract. *See* Ex. 10, at 5, 6.

137. Pfizer delegated some management of the clinical trial at issue to Defendants Icon and Ventavia, as previously explained.

138. Under the contract, Pfizer sends monthly invoices to DoD at $19.50 per dose for each delivery of vaccines, which are paid within thirty days. *See* Ex. 10, at 17.

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[6] https://www.hhs.gov/about/news/2020/07/22/us-government-engages-pfizer-produce-millions-doses-covid-19-vaccine.html.

139. In late December of 2020, DoD exercised a contractual option to purchase 100 million more doses of the vaccine for $1.95 billion. Thus, the contract's total value is now $3.9 billion.

2. FAR Compliance

140. In performing under the contract at issue, Pfizer must comply with Federal Acquisition Regulations ("FAR"), including but not limited to the provisions discussed below. *See* 42 C.F.R. §§ 3.1004(a), 52-203.13; Ex. 4, Form FDA-1571, at 2; Ex. 7, Clinical Trial Protocol, at 116.

141. FAR 52.203-13 contains the Contractor Code of Business Ethics and Conduct. In relevant part, that regulation requires Pfizer to maintain a code of ethics and conduct, exercise due diligence to prevent criminal conduct, and disclose any credible evidence that a subcontractor (including Icon and Ventavia) has committed a False Claims Act violation. 48 C.F.R. § 52.203-13(b). This regulation also requires Pfizer to maintain an "internal control system" with procedures in place to detect fraud and improper conduct "in connection with Government contracts." 48 C.F.R. § 52-203.13(c)(2). Pfizer must include the Contractor Code of Business Ethics and Conduct in any subcontract with a performance period over 120 days. 48 C.F.R. § 52-203(13)(d)(1).

142. FAR 42.202(e)(2) requires Pfizer to manage all of its subcontracts. *See* 48 C.F.R. § 42-202(e)(2). Pfizer was therefore required to monitor Ventavia and Icon's performance and ensure that they complied with the clinical trial protocol. *Id.*

3. FAR Certification

143. Federal Acquisition Regulation 52.232-32 requires Pfizer to certify the following, in relevant part, in any request for payment under the contract:

> I certify to the best of my knowledge and belief that-
> (1) This request for performance-based payment is true and correct; this request (and attachments) has been prepared from the books and records of the Contractor, in accordance with the contract and the instructions of the Contracting Officer[.]

48 C.F.R. § 52.232-32(m).

VIII. Defendants' Fraud on the Government

144. Defendants' conduct in the clinical trial at issue violates its own stated protocols, FDA regulations, and FAR, as described further below. Defendants fraudulently misrepresented their regulatory and protocol compliance to the United States and submitted false data in support of the clinical trial at issue.

A. Violation of Clinical Trial Protocol

145. Relator observed noncompliance with virtually every aforementioned provision of the clinical trial protocol at issue, as explained further below.

146. Every violation of the clinical trial protocol is a violation of the False Claims Act. Defendants represented to the United States in FDA forms 1571 and 1572 that they would abide by the protocol. *See* Ex. 4, Form FDA-1571; Ex. 5, Form FDA-1572. Defendants' regulatory noncompliance rendered Pfizer's later claims for payment fraudulent.

147. Additionally, the clinical trial protocol is a false record material to Pfizer's claims for payment. Pfizer submitted the protocol to the United States alongside its IND. Defendants' protocol noncompliance rendered the protocol false, and DoD would not have paid for the vaccines if it had known of Defendants' widespread noncompliance with the submitted protocol.

1. Inclusion and Exclusion Criteria

148. Ventavia enrolled and injected ineligible clinical trial participants.

149. Pregnant individuals are ineligible, and the trial protocol contains multiple layers of safeguards to prevent administration of the vaccine or placebo to them. *See* Ex. 7, Clinical Trial

Protocol, at 42, 44, 52, 65, 73, 86, 88, 132–35. Women of childbearing potential ("WOCBPs") and their partners must provide information about and use certain methods of contraception. *See* Ex. 7, at 44, 73, 86, 88, 132–35. WOCBPs also undergo a pregnancy test at every vaccination appointment during the trial, as previously noted.

150. Due to Ventavia's carelessness and rush to enroll and inject as many patients as possible, however, pregnant women appear to have been enrolled in the clinical trial and injected with the vaccine or placebo. *See* Ex. 12, E-mail Chain with Raney (Sept. 17, 2020), at 3, 5–6 (describing injection of pregnant patient after a positive pregnancy test). Ventavia did not report all clinical trial participants' pregnancies to Pfizer and Icon as required. *See* Ex. 7, at 67–68, 128 (required reporting protocol).

151. Women who have undergone a tubal ligation may still become pregnant. The clinical trial protocol does not list tubal ligation as an accepted contraception method. *See* Ex. 7, at 134. As a result, Ventavia was required to ensure that these women provided other contraception information and that pregnancy tests were administered before injection with BNT162b2 or placebo. Ventavia instead treated these women as non-WOCBPs, violating the clinical trial protocol. *See* Ex. 11, Ventavia's Quality Control Findings, at 3 (Subject 1018, seen at Keller site, had tubal ligation, but pregnancy test was not given). Ventavia's violations in this regard would be obvious from the source documents. Pfizer and Icon ignored these red flags and kept the ineligible participants' data in the clinical trial.

152. Ventavia's recklessness also resulted in other ineligible participants being enrolled and injected. The errors were not timely "caught" or corrected, due to Ventavia's recklessness and long-delayed "quality control" of source documents.

153. For example, Subject 11281302 was enrolled and injected before routine laboratory work and a nasal swab COVID-19 test. The subject also did not give informed consent until after injection. If this subject was COVID-19 positive, that would have rendered him or her ineligible. Furthermore, the failure to obtain informed consent is itself a protocol, regulatory, and ethical violation. When "quality checking" this subject's documents, furthermore, Ventavia edited a question about why injection preceded informed consent, transforming it into a comment that the informed consent time was incorrect:

VRG VENTAVIA RESEARCH GROUP

Quality Assurance Checklist – Source Documents

Protocol: C4591001 Subject #: 11281302 Subject Initials: S-B

Visit	Page #	Finding	QCd by: (Init/Date)	Responsible Staff	Corrected by: (Init/Date)
*		Random pg in chart	GL		
V1	3	Initial/Date note	GL	TS	
		for EXC #22			
V1	12	Pt vxcs held for	GL	AS	
		over 2 hours after			
		dose?			
V1	9	Labs/Nasal collected	GL	TS	
		after pt dosed?			
V1	9	Labs/nasal weren't	GL	NM	
		collected until after dose			
		but checked off prior			
		to dosing			
~~V1~~	~~10~~	~~why Dose time prior~~	GL		
		~~to ICF?~~			
V1	1	ICF time recorded incorrectly	GL	TS	

Ventavia subsequently would have "corrected" this patient's records to hide the informed consent and ineligibility violations, creating false source documents.

154. Relator also observed that Ventavia employees and their family members were enrolled in the clinical trial, in direct breach of the protocol, creating a serious conflict of interest.

2. Blinding

155. The clinical trial at issue is observer-blinded. At each study site, only those administering the vaccine and placebo are unblinded. *See* Ex. 7, at 47–49. Thus, the only unblinded people at Ventavia's study sites should have been those vaccinating patients: Kandy Downs, Nadia Martinez, Jailyn Reyes, and Cordy Henslin. However, Ventavia's recklessness in product and document handling led to more people becoming unblinded—including Relator, Fisher, and Fort Worth Site Operations Manager Jennifer "Jen" Vasilio. More people were likely unblinded as well, since the conduct described below had the potential to unblind patients and anyone working at Ventavia's Fort Worth and Keller locations.

156. On September 16, 2020 Relator photographed BNT162b2 vaccine boxes left out in the open at Ventavia's Fort Worth location, and later sent her photos to management. These boxes were marked as such and bore numbers that allow determination of whether a patient received a placebo or the Pfizer-BioNTech vaccine. This type of unblinding incident had occurred before at least once. *See* Ex. 13, Unblinding E-mail Chain (Sept. 22, 2020), at 1 (describing a similar incident witnessed one month prior by Downs). Neither unblinding was ever reported to Pfizer. Instead, Fisher directed Relator and others to discipline the responsible employees. *Id.*

157. On or around September 14, 2020, Ventavia discovered that randomization confirmation pages had improperly been placed in every patient's chart. These pages unblind the reader by revealing whether or not the patient received a placebo, and had been in place since the

beginning of Ventavia's involvement in the Pfizer-BioNTech trial. Approximately 1,200 patients' charts were affected, compromising the integrity of the trial. Ventavia subsequently removed or "lined through" (crossed out) this information, but it had been visible and accessible to all employees and patients for over two months. Ventavia did not report this issue to Pfizer or Icon, instead placing Notes to File ("NTFs") in patients' charts, dated September 17, 2020 and stating:

> This Note to File serves as notification that confirmation printouts of research participant drug assignments will not be placed within participant charts for study C4591001. Inclusion of the drug assignment confirmation will disclose drug dosage information contraindicated for study blinding. It is for this purpose that the confirmation of drug assignment is located in Complion within the unblinded binder. This note to file addresses IMPALA drug assignment confirmation requested in study source document versions 1 through 5.
> An update [to] the source document removing this requirement has been created in follow-up to this Note to File.

Ex. 14, NTF on Randomization, at 1. The NTFs are not viewable by Pfizer or Icon until the end of the clinical trial. The NTF on randomization, furthermore, does not show that patients and staff could have been unblinded; it simply states that randomization documents should not be in patients' charts. *See id.* However, Pfizer was alerted to the issue via a "red flag" e-mail chain from September 14–18, 2020, sent to Dr. Arturo Alfaro of Pfizer. Downs asked Alfaro to confirm that randomization forms should not be given to blinded staff, and Alfaro concurred. *See* Ex. 15, E-mail Chain with Downs and Alfaro, at 1–2. Pfizer should have realized that Downs' inquiry could indicate that the unblinding had already occurred. To Relator's knowledge, Pfizer never followed up on the issue or removed affected patients' data from the clinical trial, resulting in fraud on the United States DoD.

158. Ventavia's unblinded vaccinators also carelessly forwarded and shared communications marked "UNBLINDING"—intended only for unblinded staff—to staff who should have been blinded. For example, on September 15, 2020, Recruitment Specialist Cordy

Henslin forwarded such an e-mail to Relator. Ex. 16, E-mail Chain with Henslin, at 1. The e-mail was originally sent by Icon to Henslin, and contained subject numbers, placebo dosing information, and other data that unblinded Relator. *See* Ex. 16, at 1–4.

159. During her employment, Relator observed that the Pfizer-BioNTech vaccine containers were stored in a manner that could unblind Ventavia staff and patients. Specifically, the vaccines for all vaccine trials at Ventavia were stored together, and the vaccines for this trial were labeled with each patient's subject identification number after randomization. The vaccines are often left outside of cabinets while thawing, exposing that unblinding information to all in the vicinity. The vaccine preparation area is accessible by any staff member and even visible by patients—especially when patients were placed in hallways for "observation" after injection. To provide an illustration, if an employee was blinded for the trial at issue, but unblinded on another trial, she would be able to see patients' IDs and drug assignment for the trial at issue every time she went to the vaccine preparation area—becoming unblinded.

160. When Relator joined Ventavia, she was given lists of action items that predated her employment. Based on that documentation, inadvertent unblinding was also an issue at Ventavia's Keller location.

161. The above conduct constituted reportable violations of the clinical trial protocol which compromised the integrity of the entire study and should have been reported to Pfizer and Icon, per the protocol. *See* Ex. 7, at 54–55, 116. However, when Relator reported unblinding concerns to Ventavia management, for example, she was instructed to "write up" Fort Worth's vaccinators for discipline. Management appeared more concerned with punishing employees than investigating the extent of the unblinding. Unblinding incidents were never reported to Pfizer during Relator's employment, and were documented only in NTFs.

3. Temperature Control

162. Ventavia, in violation of temperature control requirements in the clinical trial protocol and product manual, did not report all temperature excursions to Pfizer, and did not always properly segregate vaccines affected by excursions.

163. For example, around September 11, 2020, a freezer at Ventavia's Keller location was unplugged and moved, resulting in a temperature excursion. The excursion was reported to Pfizer late, in violation of the protocol's requirement that excursions be reported as soon as discovered. The Fort Worth site also had unreported temperature excursions.

4. Informed Consent

164. Ventavia performed screening and injected clinical trial patients prior to obtaining informed consent, in direct violation of the clinical trial protocol. *See* Ex. 7, at 54, 117.

165. For example, on July 30, 2020, Ventavia recorded identical informed consent and vital sign collection times for Subject 1001 at Keller—an impossibility. Ex. 11, Ventavia's Quality Control Findings, at 1 ("[informed consent form] time same as [vital signs] Rest"). Relator observed that this often was due to vital signs being taken during or before the informed consent process. She also observed that the issue was often corrected during "quality control" by falsifying the time of vital signs to several minutes after informed consent. This is likely what was done to "correct" Subject 11281001's source documents. Similar issues were observed for the following clinical trial participants, and were likely corrected via falsification:

Subject Number	Site	Visit Type	Date of Visit	Reflected in
1004	Keller	Eligibility Screening	July 30, 2020	Ex. 11, at 1
1007	Keller	Eligibility Screening	July 30, 2020	Ex. 11, at 2
1010	Keller	Unspecified	July 30, 2020	Ex. 11, at 2
1011	Keller	Unspecified	July 30, 2020	Ex. 11, at 2
1013	Keller	Unspecified	July 30, 2020	Ex. 11, at 2
1083	Keller	Unspecified	Aug. 11, 2020	Ex. 11, at 5
1087	Keller	Unspecified	Aug. 11, 2020	Ex. 11, at 5

Subject Number	Site	Visit Type	Date of Visit	Reflected in
1088	Keller	Unspecified	Aug. 12, 2020	Ex. 11, at 5
1090	Keller	Unspecified	Aug. 12, 2020	Ex. 11, at 5
11281007	Fort Worth	First Injection	July 31, 2020	Ex. 11, at 12
11281010	Fort Worth	First Injection	July 31, 2020	Ex. 11, at 13
11281011	Fort Worth	First Injection	July 31, 2020	Ex. 11, at 13
11281012	Fort Worth	First Injection	July 31, 2020	Ex. 11, at 14

166. This issue was also observed as a recurring problem by Fisher on September 21, 2020. *See* Ex. 17, Fisher's List of Deficiencies, at 2–3 (describing ongoing informed consent timing errors and need for correction).

167. To give another example, on August 5, 2020, Subject 11281035's progress notes were written prior to execution of informed consent. *See* Ex. 11, Ventavia's Quality Control Findings, at 3.

168. A Ventavia-internal quality assurance checklist circulated by Livingston on September 22, 2020 documenting common documentation errors at Ventavia noted that the incorrect version of the informed consent form was often used, informed consent forms sometimes had "obvious mismatch[es]" in signatures (indicating possible forgery of patient signatures), and other problems. Ex. 18, Common Quality Assurance Findings Checklist, at 1.

169. Ventavia likely falsified informed consent times in order to hide these protocol deviations from Pfizer and Icon. However, Pfizer and Icon had access to the original source documents in many cases, imparting constructive knowledge of informed consent time discrepancies. *See* Ex. 19, E-mail Chain with Icon (Sept. 21, 2020), at 1, 3, 4–5 (noting informed consent date errors). Pfizer also received e-mails from Ventavia indicating past informed consent protocol violations. *See* Ex. 20, Informed Consent E-mail Chain with Alfaro and Others (Sept. 24, 2020). Had Pfizer reviewed data as required, it would have noticed this issue and removed these patients' data from the clinical trial, but it did not.

170. Ventavia never reported its informed consent violations to the IRB overseeing the clinical trial.

5. Dose Preparation

171. Ventavia routinely rushed preparation of BNT162b2 frozen concentrate, in violation of the clinical trial protocol and resulting in potential unblinding of clinical trial participants. Livingston directed employees to hold the frozen concentrate in their hand to thaw it faster than the mandated thirty minutes. *See* Ex. 6, Product Manual, at 47, 53, 56, 72, 76; Ex. 9, E-mail Chain with Downs and Others, at 1–2, 4; Ex. 21, Daily Status Updates E-mail Chain, at 51–53. Ventavia did this to maximize the number of patients injected per day and their per-patient payments from Pfizer.

172. Ventavia was also using an outdated product manual that set a thaw time of twenty, rather than thirty minutes. *See* Ex. 9, at 4. Pfizer notified Ventavia of this in August of 2020, and was placed on notice that Ventavia was likely deviating from thaw time protocols. *See id.* The issue persisted, however. On September 21, 2020, Fisher listed injection wait times of less than thirty minutes as a consistent issue, finally suggesting protocol deviation reporting and resolution with an NTF. *See* Ex. 17, Fisher's List of Deficiencies, at 2. However, to Relator's knowledge, Pfizer never removed the affected patients' data from the clinical trial.

6. Administration

173. Ventavia, in violation of the clinical trial protocol, used improperly-trained vaccinators. Cordelia "Cordy" Henslin ("Henslin"), a medical assistant, was qualified to vaccinate, but was trained over the telephone instead of in-person. And, that training did not occur until after Henslin had already started giving BNT162b2 to patients in the Pfizer-BioNTech trial.

174. Issues with Henslin were discussed via e-mail. Ray noted on August 28 that she was uncomfortable with Henslin being "the only unblinded vaccinator for this trial" at her site, and asked for a more experienced person to give training. Ex. 21, Daily Status Updates E-mail Chain, at 29. Raney replied: "I actually feel like this was brought up a few weeks ago…that [Henslin] had no training and has very little oversight [because] she is the unblinded." Ex. 21, at 28. Raney expressed concern that "something bad is going to happen with" Henslin unless she was trained. Ex. 21, at 29. On August 31, 2020, Downs acknowledged via e-mail that Henslin had finally been trained but over the telephone, and only later "rechecked when onsite." Ex. 21, at 27.

175. Additionally, other vaccinators were unqualified to administer BNT162b2. Nadia Martinez, an office assistant at the Fort Worth site, who had no medical certifications or background, acted as an unblinded vaccinator in the Pfizer-BioNTech trial. *See* Ex. 22, E-mail Chain with Fisher, Raney, and Others (Sept. 9, 2020), at 2. Ventavia was seeing so many patients that the qualified vaccinator at that site, Jailyn Reyes, was unable to perform all vaccinations. *See id.*; Ex. 23, E-mail Chain with Livingston, Vasilio, and Others, at 2 ("Nadia is now doing all the vaccines for the COVID trial, to eliminate this from Jailyn's plate, occasionally if Nadia is behind or not in office, then Jailyn will jump in to vaccinate").

176. Many clinical trial participants were given their second injection outside of the protocol-mandated nineteen to twenty-three day window. Relator and others reported this to Ventavia staff multiple times. *See*, *e.g.*, Ex. 1, Text Messages with Ray and Others (Sept. 17, 2020), at 1 (noting injection "OOW", meaning out of window); Ex. 2, E-mail Chain with Ray and Others (Sept. 23, 2020), at 1 (noting "visits that are out of window"); Ex. 18, Common Quality Assurance Findings Checklist, at 1. Ventavia never reported this violation to Pfizer or Icon, but it

would have been obvious from the source documents. However, Pfizer and Icon, to Relator's knowledge, never removed these patients from the clinical trial data.

177. Multiple clinical trial participants were injected with the wrong needle size for their body weight and sex, in violation of the clinical trial protocol. For example, on August 7, 2020, Subject 11281072 was injected with the wrong size needle at Ventavia's Fort Worth site. *See* Ex. 11, Ventavia's Quality Control Findings, at 24. The same issue recurred for Subjects 11281054, 11281050, 11281047, 11281040, 11281039 at the Fort Worth site. *See* Ex. 11, at 21–24. Ventavia also did not record needle size for multiple participants, meaning that more patients could also have been injected with the wrong needle size. *See* Ex. 11, at 17, 19, 20, 24. If this issue was not concealed via needle size falsification by Ventavia, then Pfizer and Icon had constructive notice of it via the source documents, and violated regulations by not removing these patients from the clinical trial data.

178. Ventavia also improperly diluted the concentrated BNT162b2 vaccine and did not document that failure. At least four times, Ventavia employees used too much sodium chloride solution for dilution (1.7 mL versus 1.2 mL). Defendant Icon noticed the issue and informed Ventavia. Ventavia falsely told Icon that the discrepancy was due to a transcription error. See Ex. 16, E-mail Chain with Henslin (Sept. 15, 2020), at 2.

7. Safety and Patient Monitoring

179. In violation of the clinical trial protocol, clinical trial participants were not monitored under medical supervision for thirty minutes after injection. *See* Ex. 6, Product Manual, at 44, 61; Ex. 7, Clinical Trial Protocol, at 50. Ventavia's Fort Worth site, for example, had only five examination rooms. To see as many patients as possible per day, patients were instructed to wait in a hallway for thirty minutes after injection. A Ventavia receptionist or non-medically-

qualified employee periodically "checked on" the patients and asked if they were "OK." This does not rise to the level of thirty minutes of "medical supervision" required by the protocol. Ex. 7, Clinical Trial Protocol, at 50; *see also* Ex. 6, at 44. Furthermore, the period of supervision was frequently less than thirty minutes. *See* Ex. 1, Text Messages with Ray and Others (Sept. 17, 2020), at 1.

180. Ventavia's lack of patient monitoring was reported to management by Relator and by multiple employees, and acknowledged as a recurring issue. *See, e.g.*, Ex. 1, Text Messages with Ray and Others (Sept. 17, 2020), at 1; Ex. 24, Mercedes Livingston's List of Common Errors (Sept. 22, 2020), at 2. Pfizer was put on notice of Ventavia's patient monitoring violations by Relator in an anonymous post-termination telephone call to Dr. Arturo Alfaro.

181. In a September 22, 2020 list of common errors in documentation and protocol compliance, Director of Operations Mercedes Livingston acknowledged that "Patients['] location during 30 minute waiting period" after injection was an issue, and that she would train employees accordingly. Ex. 24, at 2. Livingston instructed employees as follows:

- Be in the waiting area where **the receptionist** can see the patients
- If in the hallway, a staff member needs to be in the hallway with a work station
- Patients need to be brought back into a room for 30-minute post observation period.

Ex. 24, at 2 (emphasis added). Relator observed that Ventavia's monitoring practices did not change despite Livingston's stated plan, and that non-medical personnel were still performing "observation."

182. Ventavia management perceived its patient monitoring practices as sufficient and questioned whether patient safety was really at risk. As Jones and Fisher told Relator at a September 24, 2020 meeting:

BROOK JACKSON: **Okay, if we're gonna talk about just the safety, the safety of the patient component, they know that they don't have the rooms to manage the number of patients** [for] their recruitment goals that they're putting for these sites.

MARNIE [FISHER]: That's –

WILLIAM JONES: So what would be your recommendation? As the expert?

BROOK JACKSON: As the expert – you just –

MARNIE [FISHER]: Hold that thought. And, **what are you seeing that has led to that's a safety issue –** . . . That you've seen, that's gonna be a [FDA] warning letter? That's what I mean. That detail. So we can target –

BROOK JACKSON: **But nobody would ever know if we were putting patients in the hallway and they weren't being monitored.** But –

MARNIE: **But they are, they are being checked on.** See that's what I mean, like, they are.

BROOK JACKSON: **Marnie, no, they're not.**

MARNIE: **They are! Because I see them out there. When I'm coming and going, I'm seeing people out there all the time.** They are but, now, do we have it documented? That's where I would say, "Okay…" That's what I mean by go find – okay, that's a concern. Are we documenting it? Is it clear? So we can speak to that.

Ex. 3, Transcript of September 24, 2020 Meeting Recording, at 27–28 (emphasis added).

183. Ventavia also failed to report all adverse events and Serious Adverse Events ("SAEs") to Pfizer and Icon in the clinical trial at issue.

184. On September 17, for example, Raney e-mailed Relator, Ray, Downs, Fisher, and Livingston about issues with not reporting SAEs to Pfizer and Icon. *See* Ex. 12, E-mail Chain with Raney, at 1–2. Ventavia was actually paid by Pfizer per SAE reported, making the failure all the more puzzling. *See* Ex. 12, at 1.

185. In a September 21, 2020 e-mail to Livingston, Downs, Relator, and Jones documenting ongoing issues, Fisher noted that adverse events "are not being reported correctly **or**

at all[.]" Ex. 17, Fisher's List of Deficiencies, at 1 (emphasis added). Fisher claimed that the problem was due to conflicting information from Pfizer, but emphasized that Ventavia "should follow the protocol as to how we read it and record any [adverse events] ASAP[.]" Ex. 17, at 1.

186. Pfizer and Icon had constructive notice of this issue because they had access to clinical trial participants' "electronic diary" entries, which recorded any symptoms experienced after vaccination. Pfizer and Icon could have seen that Ventavia was not reporting all of these diary entries as adverse events, as they were required to.

8. Accuracy and Completeness of Data

187. Ventavia maintained careless and sloppy documentation practices during the Pfizer-BioNTech trial, violating the clinical trial protocol's requirement that sites maintain accurate source documents supporting all information submitted to Pfizer, and verify the accuracy of all data entry. *See* Ex. 7, Clinical Trial Protocol, at 119–21. Ventavia even falsified some patient data to cover protocol violations or missing data. Pfizer and Icon, despite obvious warning signs of documentation failures in the source documents and its communications with Ventavia, turned a blind eye to the fraud and, to Relator's knowledge, did not remove affected patients' data from the clinical trial. By doing so, Pfizer and Icon violated their responsibility to quality check all study data. *See* Ex. 7, Clinical Trial Protocol, at 120.

188. Ventavia's over-enrollment of patients and rush to see as many as possible per week took its toll on documentation. Data was often missing, and as previously mentioned, ineligible patients were sometimes enrolled and injected. *See, e.g.*, Ex. 2, E-mail Chain with Ray and Others (Sept. 23, 2020), at 1 (reporting "missing charts" to Ventavia management).

189. Ventavia's most egregious data and documentation failure relates to blood samples. Patients' blood is used to establish a baseline prior to injection with the vaccine or placebo. Any

failure in timely processing or recording data from the first sample affects the baseline, which could hide subsequent changes (and possible side effects) of the vaccine that could be slow to develop. For example, white blood cell counts are a key metric and a defective baseline would affect future readings. Furthermore, blood is used to measure immune response, in other words, whether the vaccine actually works against COVID-19. Any errors in blood draw data or processing go to the heart of the clinical trial—effectiveness of BNT162b2.

190. An example blood draw log from Ventavia's Fort Worth location is attached hereto as Exhibit 25. The document shows egregious data falsification and blood processing failures that call into question the validity of all Ventavia patients' data for the clinical trial. The document reveals:

- The time that plasma samples were frozen was altered to hide delayed freezing. *See* Ex. 25, Blood Draw Data, at 1. Freeze times are completely missing for some subjects. *See* Ex. 25, at 5, 10, 18.
- The time of centrifuge insertion was altered to disguise noncompliance with required clotting times (at least thirty minutes), required centrifuge times (at least fifteen minutes), or processing delays. *See* Ex. 25, at 4, 7, 18.
- One patient's blood did not clot, but a clot time was recorded anyway. *See* Ex. 25, at 4.
- No clot time or centrifuge insertion time was recorded for some patients. *See* Ex. 25, at 7, 8, 18.
- Blood draw times are missing for some patients. *See* Ex. 25, at 15, 18, 19, 20.
- A clot time of 309 minutes is listed for Subject 11281013 at a post-injection monitoring visit (visit 3). Ex. 25, at 1. Per Relator, the responsible employee left the lab and the blood sample sat unattended, resulting in a very long clot time being recorded. The patient should have been brought back to Ventavia for a re-draw, but that was never done.
- Clot times of exactly thirty minutes are recorded for "strings" of over twenty patients in a row—a strong indicator of falsified data. *See* Ex. 25, at 13–18, 24–28.

191. The above violations are so obvious from the source documents that Pfizer and Icon had constructive notice of Ventavia's fraud. Icon also directly questioned missing blood collection and processing times on September 21, 2020 in an e-mail to Fisher, Downs, Relator, and others. *See* Ex. 19, E-mail Chain with Icon, at 1. Yet, to Relator's knowledge, Pfizer and Icon never removed affected patients from the clinical trial data.

192. Ventavia "quality checked" patients' source documents after seeing each patient, to make sure information was consistent with protocol, was not omitted, and matched up with electronically-entered information. However, due to Ventavia's push to maximize enrollment and consequent revenue, "quality control" quickly fell behind its scheduled twenty-four hour window.

193. Ventavia eventually brought in employees' friends and family members on weekends to help "catch up" on quality control. These temporary employees were not listed on delegation logs. Furthermore, some of the temporary employees were also clinical trial participants—a serious conflict of interest.

194. Relator observed that quality control personnel were not fixing deficiencies in documentation. She personally observed employees change data during "quality checking." For example, in late September of 2020, she observed employee Thea Sonnier ("Sonnier") change blood pressure readings in source documents, apparently fabricating new numbers. Sonnier was one of the lead employees for "quality checking" and her practices would have been followed by other employees at Ventavia.

195. Ventavia management was well aware of serious documentation issues—including falsification of data—as far back as August 13, 2020. On that day, Fisher sent a company-wide e-mail emphasizing the importance of filling out source documents "real-time." Ex. 26, Source Documentation E-mail Chain, at 1. Fisher noted that if data was completed after-the-fact:

> the time has passed so data or assessments have been forgotten, source may already have been scanned in, signatures were missed[,] and now the investigator is not available to sign. **This results in deviations, queries, and overall will jeopardize the integrity of the data** and ultimately our reputation and future access to studies and thus revenue coming in.

Ex. 26, at 2 (emphasis added). Nevertheless, falsification of data and incomplete documentation persisted at Ventavia, and was never completely remedied. One month later, Fisher forwarded her August 13 e-mail to Downs and Relator, noting that sites were still falling behind on documentation. *See* Ex. 26, at 1.

196. Ventavia also failed to document improper dilution of the frozen BNT162b2 vaccine concentrate. Defendant Icon noticed the issue and informed Ventavia. Ventavia falsely told Icon that the discrepancy was due to a transcription error. See Ex. 16, E-mail Chain with Henslin (Sept. 15, 2020), at 2.

197. For months, Ventavia sites did not properly track when clinical trial participants developed symptoms of COVID-19. Ventavia created a symptom log in August, but no sites used it until Downs circulated the log on September 24, 2020. *See* Ex. 27, Symptom Log E-mail Chain and Attachment (Sept. 24, 2020), at 1. The issue was documented in an NTF but Pfizer and Icon were not notified. Nevertheless, Pfizer had constructive knowledge of this failure via the NTF, and should have excluded affected patients from its trial data.

9. Adherence to Protocol

198. Defendants were required to adhere to Pfizer's clinical trial protocol, but did not. In addition to the protocol violations listed *supra*, Defendants also violated the clinical trial protocol in the following ways.

199. Ventavia did not consistently use up-to-date versions of the clinical trial protocol or BNT162b2 product manual as they were required to. *See* Ex. 9, E-mail Chain with Downs and Others, at 4; Ex. 17, Marnie Fisher's List of Deficiencies (Sept. 21, 2020), at 1.

200. Clinical trial participants were, per the protocol, to be examined/enrolled one at a time. Ventavia, however, cancelled single patients' appointments in favor of married couples or groups of friends who sought to participate in the trial. *See* Ex. 28, List of Action Items, at 14. In Ventavia's view, groups could be scheduled and seen at the same time, maximizing the number of patients (and Ventavia's payments) per day. However, seeing groups could potentially unblind patients, could violate privacy laws, and violated the clinical trial's 1:1 randomization protocol. This practice would be apparent to Pfizer and Icon from overlapping times in the source documents. Pfizer and Icon thus ignored obvious red flags of noncompliance.

201. Ventavia also did not maintain adequate principal investigator oversight. Dr. Mark Koch, the principal investigator at Ventavia's Fort Worth location, signed records for patients he did not personally or adequately examine. Sub-investigator physicians or other medical staff examined patients instead, and Dr. Koch "signed off" on the records. This issue was noted, for example, during a "quality check" of Subject 11281278's first injection visit at Ventavia's Fort Worth site, but never reported to Pfizer or Icon:

VI	13	Why did PI sign	JR		
		when Dr. E saw the			
		pt?			

The document signed by Dr. Koch constitutes a false record because he did not actually examine the patient. The same issue affected Subject 11281378's first injection visit as well:

VI	.14	Why did PI sign when Dr. E saw pt?	[illegible]	LBL	

202. To provide another example, no principal investigator signed records of Subject 1031's screening visit on August 5, 2020. *See* Ex. 11, Ventavia's Quality Control Findings, at 3. Per Relator, this indicates that there was no principal investigator oversight for that subject's visit.

203. This issue occurred because Ventavia was seeing too many clinical trial participants per day. Principal investigator and sub-investigator physicians had their own medical practices to oversee and could not stay at Ventavia test sites all day. Some investigator physicians even went back and forth from their own offices to Ventavia multiple times per day.

204. The Houston site's principal investigator, Dr. Van Tran, wanted to close his medical practice during certain times, effectively setting aside scheduled "blocks" to examine clinical trial participants at Ventavia. On August 15, 2020, Raney told Downs, Ray, Fisher, Livingston, and another employee that Dr. Tran's plan was not acceptable because the Houston site would not be able to "hit" its cap of forty patients per week, maximizing its payments from Pfizer. *See* Ex. 21, Daily Status Updates E-mail Chain, at 55–56. Raney wrote:

> I understand that [Dr.] Tran had a different plan due to his patients and practice, but we can't allow that kind of stuff to impact a high-enrolling study. I know you brought this up on our call last week, but I didn't fully grasp the impact. In the future, if you need to detour off of my recruitment guidance, I need you to seek approval first before you agree or put anything into action. You brought the detour up really quickly on our call and it was already in place when you told me about it, so it was a little too late for me to say no (though I now realize I should have). The direction was to see the 40 patients within the first 2.5 days...so that when Pfizer did increase their [weekly] cap, we'd be the first ones approved for additional drug[s] (and I did clearly explain my strategy and the rationale behind it when I gave my direction). And now, Pfizer is planning to increase their drug and [Houston] didn't hit their 40 in the first week. Honestly, that's unacceptable. I need you to figure out how 9 patients will be randomized on Monday.

Ex. 21, at 56. Raney's directive exemplifies the focus on quick enrollment over protocol compliance, and could have resulted in inadequate oversight by Dr. Tran at the Houston site.

205. Ventavia also did not report many clinical trial protocol deviations to Pfizer and Icon. The issues, as previously noted, were often buried in "notes to the file" if they were reported at all. Fisher acknowledged this as an ongoing issue on September 21, 2020, noting that she was "not sure" if deviation reports were "getting completed or not[.]" Ex. 17, Fisher's List of Deficiencies, at 3.

10. Privacy Law Compliance

206. Defendant Ventavia's Fort Worth location mishandled clinical trial participants' protected health information, in violation of the Health Insurance Portability and Accountability Act ("HIPAA") and clinical trial protocol.

207. For example, on September 16, 2020, Relator observed that a wall calendar posted near a reception area visible to all staff and patients contained patients' names, phone numbers, and health information (as a method of reminding staff to follow up with patients). Both medical and non-medical staff could see this information. That same day, Relator also observed that patient files had been left out unattended in an area where they were visible to non-medical staff.

208. On September 21, Fisher documented common findings during document "quality checking" and noted that Ventavia's test sites were inconsistent in safeguarding patients' protected health information, describing, for example, "patient folders out on counters in the clinic and face[] up with names visible[.]" Ex. 17, Fisher's List of Deficiencies (Sept. 21, 2020), at 1.

209. Ventavia employees at all three test sites regularly utilized the smartphone and computer application "Slack" for communication, including patients' names and identification numbers. Slack is not secure or HIPAA-compliant.

210. Ventavia's HIPAA violations are a violation of the clinical trial protocol, which requires compliance with all "applicable privacy laws." Ex. 7, at 116.

B. Violation of FDA Regulations

211. Defendants' clinical trial also violated FDA regulations, as explained further below. As noted previously, Icon and Ventavia are bound by FDA regulations to the same extent and degree as Pfizer. *See* 21 C.F.R. §§ 312.50, 312.52, 312.56; Ex. 7, at 116.

212. Defendants violated FDA regulations regarding IRB oversight and reporting when they failed to report additional clinical trial participant compensation, failure to follow clinical trial protocols, and informed consent violations to the clinical trial's IRB. *See* 21 C.F.R. §§ 312.66, 312.53(c).

213. Defendants violated FDA regulations when they failed to investigate and report all adverse event information received in the clinical trial at issue, and failed to notify the FDA of all potential serious risks and adverse reactions. *See* 21 C.F.R. §§ 312.32, 312.50. Defendants Ventavia and Icon violated 21 C.F.R. § 312.64(b) when they failed to immediately report all adverse events to Pfizer.

214. Defendant Pfizer violated 21 C.F.R. § 312.50 and 21 C.F.R. § 312.56 when it failed to properly oversee Defendants Ventavia and Icon and failed to ensure that they complied with the clinical trial protocol.

215. Defendants Pfizer and Icon also violated FDA regulations when they learned of Defendant Ventavia's regulatory and protocol violations and elected not to "promptly . . . secure compliance" or "discontinue shipments of [BNT162b2] and end [Ventavia's] participation" in the clinical trial. 21 C.F.R. § 312.56(b).

216. Ventavia and Icon violated 21 C.F.R. § 312.64 by failing to furnish all required reports to Pfizer, including but not limited to reports of adverse events, temperature excursions, and clinical trial protocol deviations.

217. Defendant Ventavia violated 21 C.F.R. § 312.62 by failing to maintain adequate and accurate records of BNT162b2 dispensation and clinical trial participants' case histories.

218. Defendants violated FDA regulations by failing to obtain and document informed consent for every patient prior to clinical trial participation. *See* 21 C.F.R. §§ 50.27(a), 312.60, 312.62(b).

219. Defendant Ventavia violated FDA regulations by giving BNT162b2 to subjects not under the personal supervision of the principal investigators or sub-investigators at its clinical trial sites. *See* 21 C.F.R. § 312.61.

220. Defendant Ventavia violated 21 C.F.R. § 312.61 by administering BNT162b2 to ineligible clinical trial participants and to Ventavia employees and their family members.

221. Defendants' violations of FDA regulations constitute a violation of the clinical trial protocol as well. *See* Ex. 7, Clinical Trial Protocol, at 116 (requiring compliance with all applicable laws and regulations).

222. Defendants violations of FDA regulations rendered their certifications and representations of compliance in Pfizer's claims for payment, the clinical trial protocol, Form FDA-1571, and Form FDA-1572 false.

C. Violation of FAR

223. As previously noted, Defendant Pfizer is required to comply with FAR. Defendant Pfizer did not maintain due diligence to detect and did not disclose Defendants' violations of the

False Claims Act to DoD. Defendant Pfizer has, as a result, breached its contract with DoD and violated federal regulations. *See* 48 C.F.R. § 52.023-13.

224. Additionally, Pfizer did not monitor its subcontractors, Icon and Ventavia, as it was required to do by FAR 42-202(e)(2). *See* 48 C.F.R. § 42-202(e)(2).

D. Ongoing Monitoring Concerns

225. Enrollment in the trial at issue has closed (except for twelve- to fifteen-year-olds) and only required ongoing patient monitoring is still taking place. The fraud alleged herein also affects this ongoing monitoring. Due to Defendants' aforementioned fraudulent practices, data from ongoing monitoring (including possible new adverse events) may be falsified or concealed, preventing material information about BNT162b2 from reaching the United States.

E. Safety and Ethical Issues

226. Relator observed fundamental safety risks to study participants and Ventavia employees, over and above those which violate the clinical trial protocol. She also observed breaches of ethical standards required in clinical trials.

227. On September 16, Relator observed used needles placed in biohazard bags instead of sharps containers. The bags are not puncture-proof, so Ventavia employees were directly put at risk of injury or infection during bag handling and disposal.

228. Ventavia internally requires every patient's chart to contain dosage ranges for epinephrine based weight, age, and other factors. Epinephrine is used to counter anaphylaxis if a patient has an allergic reaction to a vaccine. Relator observed and reported to Ventavia management that the protocol was not being followed. The deficiency could lead staff to incorrectly guess the correct epinephrine dosage in an emergency, putting patients' safety and lives

at risk. Relator reported this issue to Ventavia supervisors verbally and via e-mail, including on September 23 and 24, 2020. The issue was not remedied, to Relator's knowledge.

229. To adhere to industry-standard "Good Clinical Practices," Ventavia trial site employees were required to undergo training in biologics handling, occupational safety and health, and other areas. Relator strove to ensure that all employees underwent and reported their training, but was terminated before this task was complete. To Relator's knowledge, Ventavia never provided all employees with all required training.

230. Ventavia and other trial sites for the Pfizer-BioNTech trial must get IRB approval for all compensation paid to clinical trial participants. Ventavia, however, routinely gave participants gift cards as a "customer service" initiative, to apologize for long patient wait times. For example, on August 17, 2020, Ray directed Fisher and Downs as follows:

> Let your [Site Operations Managers] know that sometimes we need to use kindness to deal with difficult patients (purchase lunch, a coffee, small gift card, apologize, etc.) Make it right when they are in the office, **don't wait until they leave upset and go write reviews or report us to the IRB, FDA.** Customer service is everything.

Ex. 28, List of Action Items, at 13 (emphasis added). Providing gift cards to clinical trial participants constitutes additional patient compensation not approved by the IRB and is a breach of ethical obligations.

231. Ventavia did not report any of the above misconduct to the IRB or Pfizer.

IX. RETALIATION AGAINST RELATOR

232. Defendant Ventavia Research Group, LLC ("Ventavia") retaliated against Relator in response to her reports of, and efforts to stop, Defendants' fraud against the United States DoD.

233. Relator began her employment with Ventavia on September 8, 2020 as a Regional Director.

234. As Regional Director, Relator oversaw site managers, patient recruitment success, training completion, quality assurance completion, enforcement of communication paths, and growth plans at her assigned test sites. These duties included ensuring that Serious Adverse Event ("SAE") reports were timely submitted, and that her assigned sites created corrective action plans to address protocol deviations. Relator's job duties also included daily and weekly communication with the site operations managers of her assigned test sites and Ventavia's leadership team.

235. Relator was responsible for the duties above at two of Ventavia's three test sites for the clinical trial at issue, located in Fort Worth and Keller, Texas. The third site involved, in Houston, was overseen by another Regional Director and managed by Lovica "Kandy" Downs. The Fort Worth site was managed by Jennifer Vasilio and the Keller site was managed by Katie Benitez.

236. The principal investigators for the three sites at issue are medical doctors: Mark Koch, M.D. ("Dr. Koch") in Fort Worth, Gregory Fuller, M.D. in Keller, and Van Tran, M.D. in Houston. The doctors are not employees of Ventavia; they serve as principal investigators in addition to practicing medicine elsewhere. Ventavia and the principal investigators were paid by Pfizer for supervision of the study on a per-patient basis, with additional funds paid per SAE reported and for activities such as training.

237. Relator's direct supervisor during her employment with Ventavia was Director of Operations Marnie Fisher ("Fisher"). Her other superiors were Ventavia's Executive Directors Olivia Ray ("Ray") and Kristie Raney ("Raney") and the Chief Operating Officer, Mercedes Livingston ("Livingston").

A. Relator begins her efforts to stop fraud on the United States Department of Defense.

238. Beginning on September 8, 2020, Relator reported on a near-daily basis to Fisher and Livingston that patient safety and the integrity of the Pfizer-BioNTech vaccine trial was at risk, via telephone, conversation, and e-mail. Relator discussed virtually all of the clinical trial protocol and FDA regulatory violations she witnessed with Livingston, Raney, and Fisher, including, but not limited to: (1) enrollment and injection of ineligible trial participants; (2) falsification of data, poor recordkeeping, and the deficiency of Ventavia's documentation "quality control"; (3) deficiencies in and failure to obtain informed consent from trial participants; (4) adverse event and SAE capture and reporting; (5) failure to preserve blinding; (6) vaccine dilution errors; (7) failure to list all staff on delegation logs; (8) principal investigator oversight; (9) reporting temperature excursions; (10) patient safety issues, such as not keeping epinephrine dose information in patient charts; (11) failure to secure and record staff training required by clinical research standards; (12) use of unqualified staff as vaccinators; (13) use of biohazard bags for needle disposal; and (14) failure to properly monitor patients post-injection.

239. In general, every time that Relator raised concerns about safety or Ventavia's clinical trial protocol compliance with Fisher, she was told to e-mail Fisher about the issue or make a list of affected patients. Many of the identified issues were systemic, and Relator did not have access to information required to make the lists Fisher requested. Relator did as Fisher requested to the extent that she was able, but the identified problems were never addressed. *See* Ex. 3, Transcript of Sept. 24 Meeting (discussing, in part, Relator's prior reports of protocol violations).

240. Relator also reported some clinical trial protocol violations to the Fort Worth Principal Investigator, Dr. Koch. In particular, Relator discussed Ventavia's practice of "quality checking" patient source documents after the fact and issues of missing documentation. Dr. Koch

acknowledged that Ventavia needed to "clean up" the problems before starting any new clinical trials.

241. Ventavia was required to scan or enter all data from clinical trial participants' source documents into its Clinical Trial Management System Database, so that it could be passed on to Icon and Pfizer. Ventavia "quality checked" all source documents before scanning or uploading them. In Ventavia's scramble to enroll as many participants as possible per week and maximize revenue, quality checking and uploading fell behind schedule. Relator observed that the "back log" of documents to be quality checked often lacked key information, such as patient or doctor signatures and blood draw times. Relator also observed that Ventavia's quality checking process was performed by unqualified personnel not listed on delegation logs, and often involved falsification of missing data. Relator reported her concerns to Ventavia management, who seemed more concerned with "catching up" on quality checking than preventing fraud.

242. On September 15, 2020, Relator reported to Fisher that some patient charts had never been sent to Pfizer, were needed "urgently," and had not been quality checked. *See* Ex. 29, Text Messages with Fisher, at 1.

243. Relator called Ventavia's contact at Pfizer for the trial at issue, Dr. Arturo Alfaro ("Dr. Alfaro") on September 14 and 16 to discuss protocol violations, but was unable to reach him.

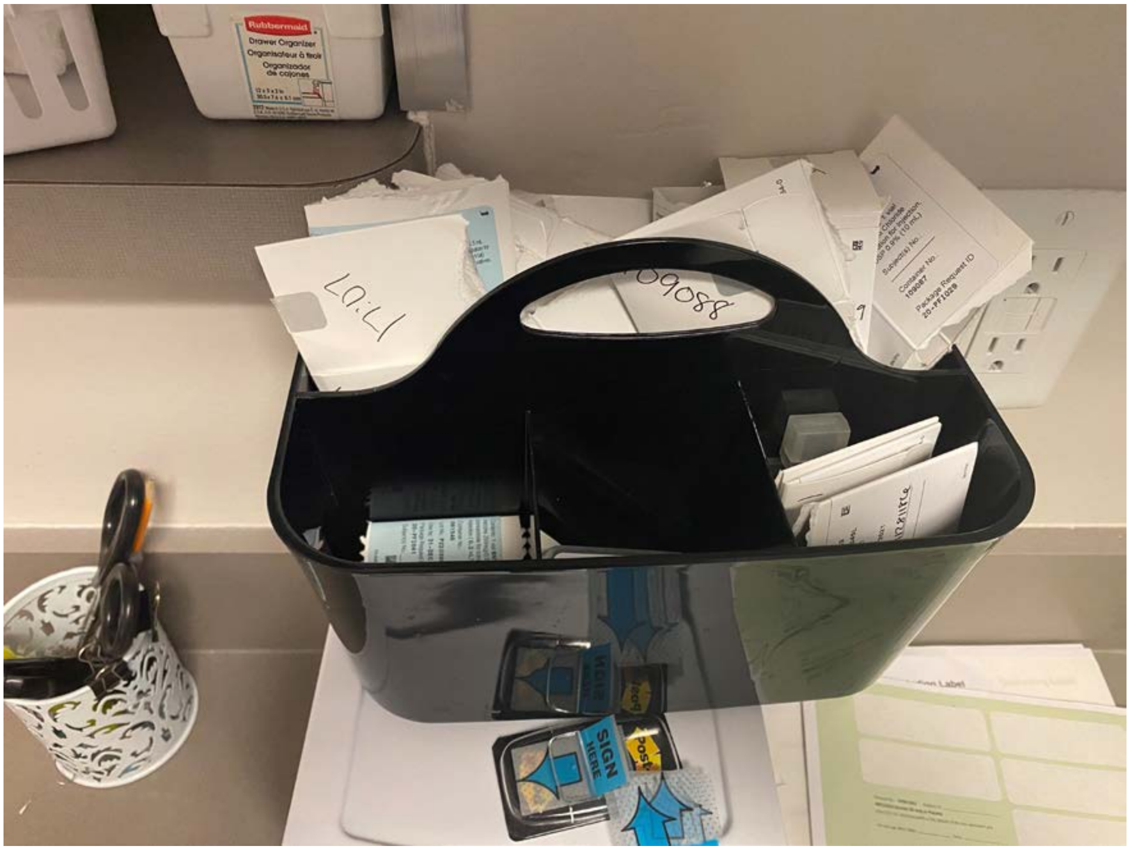
B. Relator photographs violations.

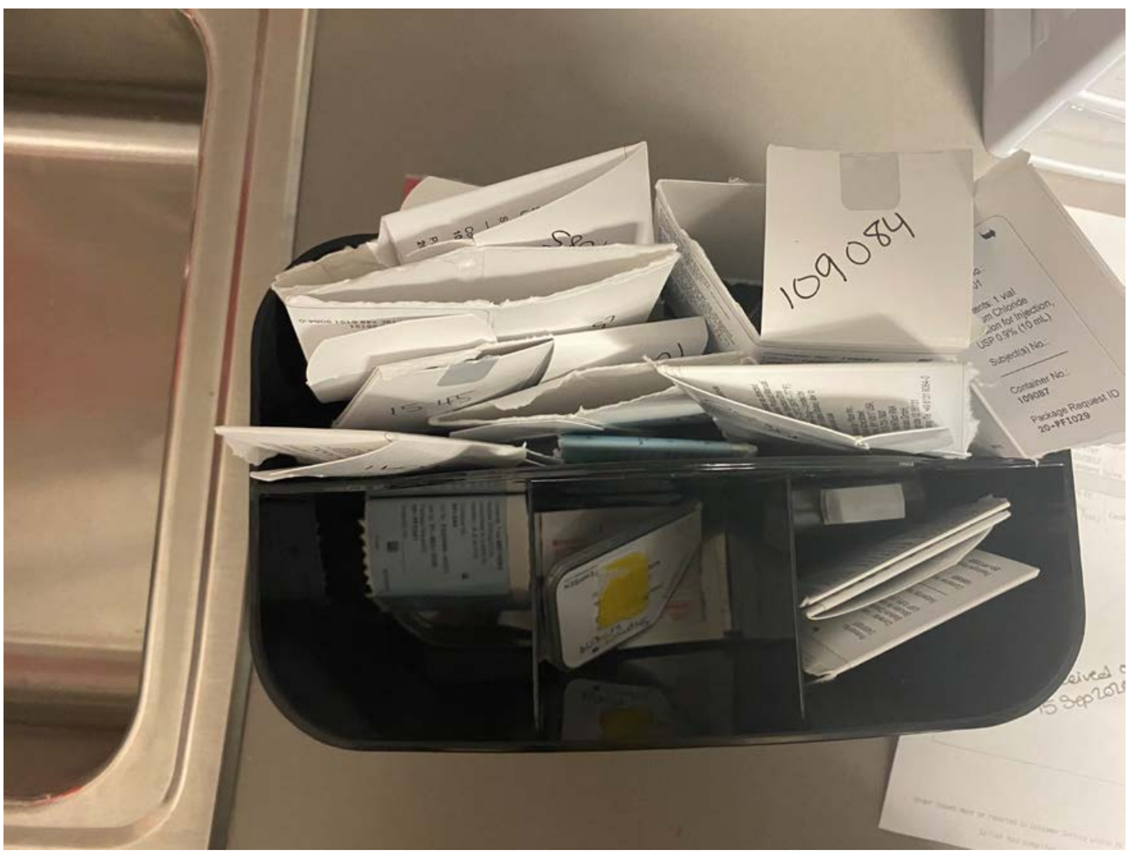
244. On September 16, 2020, Relator examined some of the biohazard disposal bags at Ventavia's Fort Worth site. She had been asked to monitor this issue because Ventavia was charged by weight for disposal of the bags, and non-biohazard items were sometimes improperly placed there. Relator discovered that used needles had been disposed of in the bags:



See also Ex. 3, Transcript of September 24 Meeting Recording, at 1–2. Biohazard bags are not puncture-proof, so this presented a serious risk to employees' safety.

245. That same night, Relator photographed ongoing HIPAA violations. Ventavia kept a calendar of patients to follow up with in public view in a reception area. The calendar contained patients' names and information. Similarly, patient records were left out in public view. Relator also documented that product cartons and patient randomization numbers from the BioNTech-Pfizer vaccine trial had been left in public view in a preparation area, potentially unblinding all Ventavia staff at the site and some patients as well:


Rubbermaid
Drawer Organizer
SIGN HERE


109084
Subject(s) No.
Container No.
Package Request ID

246. Relator shared her photographs from September 16 with Livingston and Fisher via text message or e-mail. The following day, she reported an identical biohazard bag issue at the Keller site to the same people.

C. Relator recommends pausing clinical trial enrollment.

247. On September 17, 2020, Relator spoke to Downs and Ventavia's Quality Control Director William Jones ("Jones") via telephone. Relator asked both for their opinion about what would happen if the FDA audited Ventavia. Both Downs and Jones responded the same way—afraid that Ventavia would receive warning letters or be asked to discontinue trial enrollment.

248. Later that day, in her daily phone call with Ray, Raney, Fisher, Downs, and Livingston, Relator brought up virtually all of the protocol and regulatory violations she had witnessed to date, as well as Ventavia's HIPAA violations. Relator explained that the FDA would likely issue warning letters against Ventavia if it visited or audited the trial sites. She recommended that Ventavia immediately stop enrollment in the Pfizer-BioNTech clinical trial.

249. Ray directed Relator and others to conduct FDA trainings, in preparation for a possible future site visit or audit by the FDA. *See* Ex. 28, List of Action Items, at 1; Ex. 1, Text Messages with Ray and Others (Sept. 17, 2020), at 1. Ventavia also decided to pause enrollment in order to catch up on "quality checking" source documents. *Id.*

250. Later on September 17, Relator responded to a group text message including Ray, Downs, Raney, Livingston, and Fisher. *See* Ex. 1, at 2. First, Relator passed on the concerns of Fort Worth Site Operations Manager Jennifer Vasilio regarding documentation and patient observation protocol violations, patients being injected outside of the nineteen to twenty-three day "window," and HIPAA violations. Ex. 1, at 1. Second, Relator expressed her concerns about Ventavia's "quality checking" (QC):

> I would like us to create a solid monitoring plan . . .
>
> I don't think it is as simple as pulling a chart and looking for missing check boxes or missing initial in a header/footer which I have been seeing a lot of when I have QC'd the QC'er.
>
> We need to be able to reconcile time of [vaccine] prep and admin[istration], for example. This cannot be done by everyone who is QC'ing to ensure we do maintain the blind. This is one reason I think we need to carefully consider what we are looking at especially if we are approaching this from the perspective of an FDA auditor, which I 100% think we should be. . . .
>
> I would have liked the opportunity to discuss this with [the principal investigators, Drs. Fuller and Koch] individually and I still would.

Ex. 1, Text Messages with Ray and Others (Sept. 17, 2020), at 2. The "reconcil[ing]" Relator discussed showed that vaccine preparation and administration times were not compliant with the clinical trial protocol. *Id.*

251. Ventavia was not up-front with Pfizer and Icon about the reasons for the enrollment pause (sloppy documentation that violated the clinical trial protocol). In a text message conversation on September 17, Raney instructed Ventavia employees how to respond to any questions from Pfizer about the pause. She told them to "make it like it's no big deal" and that the pause resulted from Ventavia was "being responsible by considering we have a certain bandwidth and these visits on top [of] each other has hit our bandwidth." Ex. 1, at 10. Raney also directed employees to falsely tell patients that Ventavia was not enrolling because "we met our company capacity[.]" Ex. 1, at 6. Ventavia was also not up-front with its Houston principal investigator, Dr. Van Tran, regarding the reason for the pause. Downs was directed to convey to Dr. Tran that the pause was due to Ventavia being "at capacity" and not wanting "to overd[o] it." Ex. 1, at 9.

252. Ventavia ultimately elected to schedule patients for several weeks later rather than truly and completely pause enrollment. *See* Ex. 1, at 6, 9–10. Raney directed employees not to cancel any patients already "on their way" to test sites because "that might piss them off and they

can call the news, etc[.]" Ex. 1, at 11. Livingston responded, "if [patients] were scheduled far enough out[,] cancel[,] but if they are there then see them." *Id.* Downs responded that she would not cancel patients in Houston. *See id.*

253. During the enrollment pause, Ventavia's "quality checking" not only failed to correct documentation violations but also involved falsification of missing or inconsistent data. Ventavia hired employees' friends and family members on a temporary basis to perform quality checking who were not adequately trained. Relator even personally observed employees falsifying source document data (*i.e.*, by changing blood pressure readings). Relator also noticed that information was often completely obscured when changed, rather than "lining through" (which preserves legibility of the original text). In short, Ventavia's "quality checking" failed to prevent or stop fraud on the United States DoD.

254. On September 23, 2020, Relator e-mailed Ray, Fisher, Raney, Downs, Jones, and Livingston to report ongoing serious issues with Ventavia's "quality checking." *See* Ex. 2, E-mail Chain with Ray and Others (Sept. 23, 2020). Relator noted, among other issues:

- There were 100 outstanding queries from Icon about missing or inconsistent data which were up to twenty-eight days old. *See* Ex. 2, at 1.
- Scheduling errors resulted in multiple patients receiving their second injection outside of the required nineteen to twenty-three day window. Ventavia was not truthfully recording the vaccine delay for these patients, and due to the oversight, Pfizer and Icon could not discover that these patients were vaccinated outside of the permissible window. *Id.*
- Quality checking caused large delays. Relator found a twenty-one-day-old patient chart that had not been entered into the Electronic Data Capture system to send to Icon and Pfizer. That information should have been entered within twenty-four hours. *Id.*
- Some patient charts and laboratory specimens were missing. *Id.*

Due to the seriousness of these violations, Relator noted that she "might be in a little bit of shock." Ex. 2, at 1.

255. On September 23, 2020, Relator e-mailed Livingston to report that Ventavia's emergency response protocol for allergic reactions was not being followed. Ventavia internally required every patient's chart to contain appropriate dosage ranges (based on age, weight, etc.) for epinephrine in the event of anaphylaxis. The patients' charts did not contain this information. No action was taken to correct this during Relator's employment.

D. Ventavia management falsely accuses Relator of violating patient confidentiality.

256. On the evening of September 24, 2020, Relator met with Fisher and Jones. *See* Ex. 3, Transcript of September 24, 2020 Meeting Recording. The meeting was arranged to discuss Relator's photographic documentation of safety issues, HIPAA violations, and unblinding from September 16. The meeting quickly escalated into harassment. Fisher questioned repeatedly why Relator took the photographs and falsely accused Relator of removing patient source documents from another Ventavia location. *Id.*

257. Fisher reiterated her instructions to provide specific patient names which, as noted previously, was not always possible. *See* Ex. 3, at 4, 18, 20, 22. Fisher and Jones gave contradictory instructions, telling Relator to fix violations once identified but also noting that Ventavia cannot correct all violations, and has to pick and choose what to address. *See, e.g.*, Ex. 3, at 12, 15, 27. Jones stated that Ventavia had not "even finished quantifying the number of errors" because "it's something new every day." Ex. 3, at 12. He acknowledged that the problems were "not just in one site" either, and stated "we're gonna get some kind of letter of information at least, when the FDA gets here. Know it." *Id.*

258. When Relator discussed her unblinding documentation, Fisher appeared more concerned with punishing the employees responsible for the unblinding incident than preventing the issue in the future. *See* Ex. 3, at 2, 3; *see also* Ex. 13, Unblinding E-mail Chain (Sept. 22, 2020), at 1 (instructing employees to discipline those responsible for unblinding incident).

259. Relator specifically referenced FDA regulatory violations in her conversation with Fisher and Jones. *See* Ex. 3, Transcript of September 24, 2020 Meeting Recording, at 14. She told Fisher and Jones that if they did not see what she saw when quality checking patients' source documents, then they needed to "get on Google" and search for FDA warning letters. Ex. 3, at 14.

260. Relator reported hearing Raney and Ray acknowledge via telephone that Ventavia did not have the staff or patient room capacity to handle the number of clinical trial participants being seen every day. Ex. 3, at 15. Relator questioned whether Raney and Ray truly prioritized patient safety. *See id.* Fisher questioned whether placing patients in the hallway for "monitoring" after injection was actually a safety risk. *Id.*

261. Relator also discussed with Jones and Fisher that Downs had previously reported many of the same violations and safety risks that Relator had. *See* Ex. 3, at 21, 23–24. Fisher claimed that Ventavia addressed Downs' concerns, but clearly the same issues had recurred, or else Relator would not have spotted them. *See* Ex. 3, at 24.

E. Ventavia terminates Relator the next day.

262. On the following morning, Relator called the FDA's hotline to report the clinical trial protocol violations and patient safety concerns she witnessed.

263. Relator was terminated from her position at Ventavia that same day—September 25, 2020. Relator was never formally disciplined or reported for any failure regarding her job performance until the day that she was terminated.

264. Relator was harassed and terminated by Defendant Ventavia as a direct consequence of her reports of and efforts to stop fraud against the United States DoD.

265. After Relator was terminated, she called Dr. Alfaro at Pfizer and gave a general overview of her concerns about unblinding, principal investigator oversight, and patient safety in the Pfizer-BioNTech vaccine trial. She also informed Dr. Alfaro that she had contacted the FDA. Relator did not identify herself or discuss any specific trial sites, concerned that doing so might adversely affect a future retaliation action.

266. Not long after her termination, the FDA contacted Relator and spoke to her for several hours regarding the violations she witnessed at Ventavia.

267. Almost immediately after Relator was terminated (the next business day), Ventavia lifted the enrollment "pause" and resumed the push to enroll as many clinical trial participants per week as possible. Given the amount of "quality control" left to be performed when Relator was terminated, Relator estimates that Ventavia had neither completed quality checking nor remedied its ongoing violations by the time it resumed enrollment.

268. Relator's termination is but one example of a pattern and practice of retaliatory terminations by Defendant Ventavia. Ventavia's prior Fort Worth Site Operations Manager Michelle Gaines was terminated in August of 2020 for reporting and trying to stop protocol noncompliance and regulatory violations in other clinical trials.

X. ACTIONABLE CONDUCT BY DEFENDANTS

A. False Claims Act

1. Applicable Law

269. This is an action to recover damages and civil penalties on behalf of the United States and Relator Jackson arising from the false and/or fraudulent statements, claims, and acts that Defendants made in violation of the False Claims Act, 31 U.S.C. §§ 3729–3732.

270. For conduct occurring on or after May 20, 2009, the FCA provides, in relevant part, that any person who:

> (A) knowingly presents, or causes to be presented, a false and/or fraudulent claim for payment or approval; [or]
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false and/or fraudulent claim[,]

31 U.S.C. § 3729(a)(1), is liable to the United States for a civil penalty of not less than $11,665 and not more than the applicable regulatory maximum for each such claim, plus three times the amount of damages sustained by the Government because of the false and/or fraudulent claim. *See* 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.5.

271. The FCA defines "claim" as:

> (A) mean[ing] any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that--
>
> (i) is presented to an officer, employee, or agent of the United States; or
>
> (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government--
>
> (I) provides or has provided any portion of the money or property requested or demanded; or

> (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded. . . .

31 U.S.C. §3729(b)(2).

272. The FCA allows any person having knowledge of a false and/or fraudulent claim against the Government to bring an action in federal district court for himself and for the United States, and to share in any recovery, as authorized by 31 U.S.C. § 3730.

273. Based on these provisions, Relator Jackson seeks damages and civil penalties arising from Defendants' violations of the False Claims Act.

2. Defendants' Violations of the False Claims Act

a. Presentation of False Claims (31 U.S.C. § 3729(a)(1)(A))

274. From 2020 to the present, Defendants knowingly presented, or caused the presentment of, false and/or fraudulent claims for payment or approval to the United States. Pfizer's claims for payment to DoD were rendered false and/or fraudulent by express and implied false certifications.

275. First, when Defendant Pfizer submitted its clinical trial protocol to the United States in connection with its contract, it represented that the clinical trial would comply with all applicable laws and regulations. Defendants violated FAR and multiple FDA regulations when conducting the clinical trial, rendering this certification false.

276. Second, Defendant Pfizer's IND for the vaccine and clinical trial at issue warned that making a "willfully false statement is a criminal offense." Ex. 4, Form FDA-1571, at 2. Defendants rendered Pfizer's acknowledgement of this warning false by submitting false data to the FDA.

277. Third, Defendants Ventavia and Icon certified in Form FDA-1572, submitted to Pfizer and the United States, that they would: (1) conduct the trial in accordance with the protocol and FDA regulations; (2) obey informed consent and IRB reporting requirements; (3) report adverse events; (4) ensure that all "associates, colleagues, and employees assisting in" the trial were "informed about their obligations"; and (5) make no changes to the trial without IRB approval. B, Form FDA-1572; 21 C.F.R. § 312.53(c)(vi). Ventavia and Icon acknowledged when submitting Form FDA-1572 that making willfully false statements is a crime. *See* Ex. 5, at 2. This acknowledgement and certification was rendered false by Ventavia and Icon's violations of the clinical trial protocol, FDA regulations, and fraudulent conduct described *supra*.

278. Fourth, Defendant Pfizer certified in its claims for payment that they were true and correct, prepared from Pfizer's books and records, and in accordance with the Pfizer-DoD contract. *See* 48 C.F.R. § 52.232-32(m). This certification was rendered false by Defendants' submission of false data and violation of FDA regulations and FAR, and by the other fraudulent conduct described *supra*.

279. Defendants' fraudulent schemes transform these certifications into false certifications, rendering Defendant Pfizer's claims for payment to DoD false and/or fraudulent.

280. By creating and carrying out their fraudulent schemes, Defendants knowingly and repeatedly violated Section 3729(a)(1)(A) of the False Claims Act.

281. Defendants' knowing submission, or causation of submission, of false and/or fraudulent claims had the potential to influence the government's payment decision and was material to the government's decision to pay the claims.

282. Defendants' violations of the applicable statutes and regulations, and misrepresentations regarding their compliance, were material, because they went to the very

essence of the bargain for which the United States DoD contracted. Had the United States DoD known of Defendants' fraudulent non-compliance, which resulted in the submission of ineligible false and/or fraudulent claims for reimbursement, it would not have paid the claims.

283. Defendants' presentment, or causation of presentment, of false and/or fraudulent claims to the United States DoD was a foreseeable factor in DoD's loss and a consequence of Defendants' schemes. By virtue of Defendants' actions, the United States DoD has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false and/or fraudulent claim.

b. Making or Using False Records or Statements to Cause Claims to be Paid (31 U.S.C. § 3729(a)(1)(B))

284. From 2020 to the present, Defendants knowingly made, used, or caused to be made or used, false records or statements that were material to false and/or fraudulent claims paid or approved by the United States DoD. These false records or statements include the clinical trial protocol Pfizer submitted to the United States and the falsified source documents and data behind Defendants' trial results and EUA application.

285. By creating and carrying out their fraudulent schemes, Defendants knowingly and repeatedly violated Section 3729(a)(1)(B) of the False Claims Act.

286. Defendants' false records were material to Pfizer's claims for payment for the vaccine at issue. The United States DoD would not have paid Pfizer if it knew that the clinical trial protocol was not complied with by Defendants, because the protocol violations call the integrity and validity of both the entire clinical trial and Pfizer's EUA into question.

287. Defendants' false records also went to the very essence of the bargain the United States contracted for. DoD contracted to purchase vaccines found effective by a valid clinical trial conducted according to the protocol submitted by Pfizer. The integrity of the entire clinical trial

was compromised by the trial protocol violations, false source documents, and the false data that resulted, which calls the vaccine's EUA into question. Had the United States DoD known of Defendants' false records, it would not have paid Pfizer.

288. Defendants' use, or causation of use, of material false records was a foreseeable factor in the United States DoD's loss and a consequence of Defendants' schemes. By virtue of Defendants' actions, the United States DoD has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false and/or fraudulent claim.

c. Retaliation (31 U.S.C. § 3730(h))

289. Section 3730(h) of Title 31 of the United States Code defines whistleblower protection under the False Claims Act as follows:

> (1) Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under [the False Claims Act] or other efforts to stop 1 or more violations of [the False Claims Act].
> (2) Relief . . . shall include reinstatement with the same seniority status that employee, contractor, or agent would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees.

31 U.S.C. § 3730(h).

290. As discussed *supra*, in violation of 31 U.S.C. § 3730, Defendant Ventavia retaliated against Relator as a result of Relator's efforts to stop Defendants from committing False Claims Act violations. Defendant Ventavia punished Relator for her lawful and statutorily protected activity with harassment and termination.

291. Relator has suffered both economic loss and emotional harm as a result of Defendant Ventavia's retaliatory actions.

XI. CAUSES OF ACTION

A. Count I – Presentation of False and/or Fraudulent Claims (31 U.S.C. § 3730(a)(1)(A))

292. Relator realleges and hereby incorporates by reference each and every allegation contained in all paragraphs of this Complaint.

293. Since December of 2020, Defendants have knowingly presented or caused the presentment of false and/or fraudulent claims to the United States for payment or approval. Defendant Pfizer's claims for payment to DoD were rendered false or fraudulent by Defendants' implied and express false certifications of legal and regulatory compliance, accuracy of data, and clinical trial protocol compliance.

294. By creating and carrying out their fraudulent scheme, Defendants knowingly and repeatedly violated the False Claims Act. *See* 31 U.S.C. § 3729(a)(1)(A).

295. Defendants' knowing submission, or causation of submission, of false and/or fraudulent claims had the potential to influence the United States' payment decision and was material to the United States' decision to pay the claims.

296. The United States paid the false and/or fraudulent claims.

297. Defendants' presentment or causation of presentment of false and/or fraudulent claims was a foreseeable factor in the United States' loss and a consequence of Defendants' fraudulent scheme. By virtue of Defendants' actions, the United States has suffered damages and is entitled to recover treble damages plus a civil monetary penalty for each false and/or fraudulent claim.

B. Count II – Making or Using False Records or Statements Material to False and/or Fraudulent Claims (31 U.S.C. § 3730(a)(1)(B))

298. Relator realleges and hereby incorporates by reference each and every allegation contained in all paragraphs of this Complaint.

299. From 2020 to the present, Defendants knowingly made, used, or caused to be made or used, false records or statements that were material to false and/or fraudulent claims paid or approved by the United States. These false records or statements include the clinical trial protocol that Defendant Pfizer submitted to the United States and the falsified source documents and data behind Defendants' clinical trial results and Emergency Use Authorization application.

300. By creating and carrying out their fraudulent scheme, Defendants knowingly and repeatedly violated 31 U.S.C. § 3729(a)(1)(B).

301. Defendants' false records or statements, or causation thereof, had the potential to influence the United States' payment decision and were material to the United States' decision to pay the claims.

302. Defendants' false records or statements, or causation thereof, were material because they went to the very essence of the bargain for which the United States contracted. Had the United States known of Defendants' fraudulent misrepresentations regarding the clinical trial at issue, which resulted in the submission of ineligible false/fraudulent claims for reimbursement, then the United States would not have paid those claims.

303. The United States paid the false and/or fraudulent claims.

304. Defendants' false records or statements, or causation thereof, was a foreseeable factor in the United States' loss and a consequence of Defendants' scheme. By virtue of Defendants' actions, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false and/or fraudulent claim.

PRAYER FOR RELIEF

305. WHEREFORE, Relator prays that this Court enter judgment against Defendants and award the following:

(1) Damages in the amount of three (3) times the actual damages suffered by the United States as a result of Defendants' conduct;

(2) Civil penalties against Defendants up to the maximum allowed by law for each violation of 31 U.S.C. § 3729;

(3) The maximum award Relator may recover pursuant to 31 U.S.C. § 3730(d);

(4) All costs and expenses of this litigation, including attorneys' fees and costs of court; and

(5) All other relief on behalf of Relator or United States that the Court deems just and proper.

C. Count III – Retaliation (31 U.S.C. § 3730(h))

306. Relator realleges and hereby incorporates by reference each and every allegation contained in all paragraphs of this Complaint.

307. In violation of 31 U.S.C. § 3730(h), Defendant Ventavia Research Group, LLC ("Ventavia") retaliated against Relator Jackson as a result of her efforts to stop Defendants from committing violations of the False Claims Act.

308. Ventavia punished Relator for her lawful and statutorily protected activity with harassment and termination.

309. Relator has suffered economic loss and emotional harm as a result of her termination by Ventavia.

PRAYER FOR RELIEF

310. WHEREFORE, Relator prays that this Court enter judgment against Defendant Ventavia Research Group, LLC for the following:

(1) Reinstatement with the same seniority status;

(2) Two times the amount of Relator's back pay;

(3) Interest on Relator's back pay;

(4) Compensation for special damages sustained by Relator as a result of Defendants' actions, including but not limited to compensatory damages for emotional pain, suffering, inconvenience, mental anguish, loss of enjoyment of life, loss to reputation, and other pecuniary and nonpecuniary losses;

(5) Punitive damages;

(6) Litigation costs and attorneys' fees;

(7) Prejudgment interest at the highest rate allowed by law; and

(8) Any other relief that the Court deems just and proper to make Relator whole.

XII. INDEX OF EXHIBITS

311. The exhibits referenced herein consist of the following:

Exhibit Number	Description	Bates Range
1	Text Messages with Ray and Others (Sept. 17, 2020)	JSN0001-JSN0011
2	E-mail Chain with Ray and Others (Sept. 23, 2020)	JSN0012-JSN0014
3	Transcript of September 24, 2020 Meeting	JSN0015-JSN0046
4	Form FDA-1571	JSN0047-JSN0049
5	Form FDA-1572	JSN0050-JSN0051
6	BNT162b2 Product Manual	JSN0052-JSN0135
7	Clinical Trial Protocol	JSN0136-JSN0281
8	Pfizer Press Release (Nov. 18, 2020)	JSN0282-JSN0287
9	E-mail Chain with Downs and Others (Sept. 18, 2020)	JSN0288-JSN0292
10	Pfizer-DoD Contract	JSN0293-JSN0327
11	Ventavia's Quality Control Findings	JSN0328-JSN0351
12	E-mail Chain with Raney (Sept. 17, 2020)	JSN0352-JSN0357
13	Unblinding E-mail Chain (Sept. 22, 2020)	JSN0358-JSN0359
14	Note to File on Randomization (Sept. 17, 2020)	JSN0360
15	E-mail Chain with Downs and Alfaro	JSN0361-JSN0364
16	E-mail Chain with Henslin (Sept. 15, 2020)	JSN0365-JSN0369
17	Marnie Fisher's List of Deficiencies (Sept. 21, 2020)	JSN0370-JSN0373
18	Common Quality Assurance Findings Checklist (Sept. 22, 2020)	JSN0374-JSN0377
19	E-mail Chain with Icon (Sept. 21, 2020)	JSN0378-JSN0385
20	Informed Consent E-mail Chain with Alfaro and Others (Sept. 24, 2020)	JSN0386-JSN0391
21	Daily Status Updates E-mail Chain	JSN0392-JSN0457
22	E-mail Chain with Fisher, Raney, and Others (Sept. 9, 2020)	JSN0458-JSN0460
23	E-mail Chain with Livingston, Vasilio, and Others (Sept. 22, 2020)	JSN0461-JSN0464

Exhibit Number	Description	Bates Range
24	Mercedes Livingston's List of Common Errors (Sept. 22, 2020)	JSN0465-JSN0467
25	Blood Draw Data	JSN0468-JSN0495
26	Source Documentation E-mail Chain (Sept. 10, 2020)	JSN0496-JSN0497
27	Symptom Log E-mail Chain and Attachment (Sept. 24, 2020)	JSN0498-JSN0503
28	List of Action Items	JSN0504-JSN0521
29	Text Messages with Fisher (Sept. 14-15, 2020)	JSN0522

XIII. DEMAND FOR JURY TRIAL

312. Pursuant to Federal Rule of Civil Procedure 38, Relator demands a trial by jury.

Respectfully submitted,

BERG & ANDROPHY

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CERTIFICATE OF SERVICE

I hereby certify that on January 8, 2021, a true and correct copy of the foregoing was delivered to the following recipients via certified mail, return receipt requested.

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____*/s/ Joel M. Androphy*_____
Joel M. Androphy